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No.

Supreme Court, U.S.
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IN THE

Supreme Court of the United States

OCTOBER TERM, 1988

RALPH NADER, *et al.*,
Petitioners,

v.

ENVIRONMENTAL PROTECTION AGENCY,
et al.,
Respondents.

APPENDIX TO PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

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FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

RALPH NADER, NATURAL RESOURCES DEFENSE COUNCIL, STATE OF NEW YORK, PUBLIC CITIZEN, MARK BEYELER, et al.,
Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,
Respondent,

and

UNIROYAL CHEMICAL COMPANY, et al.,
Respondent-Intervenors.

No. 87-7103
OPINION

Petition for Review of Decision of The Environmental Protection Agency

Argued and Submitted
March 14, 1988—San Francisco, California

Filed October 14, 1988

Before: Richard H. Chambers, Mary M. Schroeder and Betty B. Fletcher, Circuit Judges.

Opinion by Judge Fletcher

SUMMARY

Environmental Law/Administrative Law

Dismissing a petition for review, the court found, in this case, that the EPA's denial of a citizens' rulemaking petition may not be directly appealed to this court pursuant to 21 U.S.C. §§ 346a(i) and 348(g).

After several disputed scientific studies suggested that the pesticide daminozide may cause tumors, respondent EPA conducted a special review to decide whether to revoke daminozide's tolerance levels. On the basis of its Scientific Advisory Panel's decision, the Agency decided not to revoke the tolerances. Instead, it proposed to reduce the tolerance from 30 parts per million to 20 ppm. While EPA's proposed rule was still pending, petitioners filed a petition under sections 346a and 348 asking the Agency to revoke the tolerance altogether. The EPA denied the section 346a petition and reduced the tolerance for daminozide. The issue is whether the EPA's denial of a citizens' rulemaking petition may be directly appealed to this court pursuant to sections 346a(i) or 348(g).

[1] Section 348(b) permits any person to file a petition proposing regulations for the use of food additives. The Administrator must then either establish a regulation or deny the petition. **[2]** Within 30 days after publication of either, any person adversely affected by such an order may file objections and request a hearing. Section 348(f)(1). **[3]** Should an actual controversy arise under subsection (f), section 348(g) permits review of such an order in court. To obtain review, a petition must be filed within 60 days. **[4]** After their petition was denied, petitioners did not file objections with the Administrator under subsection (f). Since more than 30 days have now elapsed, they cannot allege jurisdiction under 348(g). **[5]** Section 346a(i) grants the courts of appeals jurisdiction to review

the validity of any order under section 346a(e). Section 346a(e) provides that upon the request of an interested person, the Administrator may propose the issuance of a regulation establishing a tolerance. By its terms, section 346a(e) accords the Administrator considerable latitude in determining whether to grant a request to propose a tolerance. **[6]** Furthermore, section 346a(e) denominates as an order only one act of the Administrator: the publishing of a regulation. Subsection (i) authorizes review only of *orders,* not of every act by which a petitioner is aggrieved. **[7]** Nor is the denial of a rulemaking petition within the meaning of order as that term is defined in the Administrative Procedure Act. **[8]** If parties were free simply to file petitions, await their denial, and then be assured of jurisdiction in the court of appeals, there would be little incentive to comply with the procedural provisions of the FDCA that require direct appeals from a regulation to be made within the statutory time period.

COUNSEL

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OPINION

FLETCHER, Circuit Judge:

This case requires us to decide for the first time whether the EPA's denial of a citizens' rulemaking petition may be

directly appealed to this court pursuant to 21 U.S.C. § 346a(i) or 21 U.S.C. § 348(g).

After several disputed scientific studies suggested that the pesticide daminozide may cause tumors, respondent EPA conducted a special review to decide whether to revoke the tolerance for daminozide. On the basis of its Scientific Advisory Panel's decision that the studies were inconclusive, the Agency decided not to revoke the tolerances. Instead, it proposed in April, 1986, to reduce the tolerance from 30 parts per million to 20 ppm. In July 1986, while EPA's proposed rule was still pending, petitioners filed a petition under 21 U.S.C. §§ 346a and 348 asking the Agency to revoke the tolerance altogether. 21 U.S.C. § 346(e) provides that the Administrator "may" propose regulations when asked by an interested person to do so, but imposes no express duty on the Administrator. On January 6, 1987, EPA denied the petition. Ten days later, on January 16, it published a final regulation reducing the tolerance for daminozide from 30 ppm to 20 ppm.

Petitioners appeal the denial of their petition. They contend that 21 U.S.C. §§ 346a(i) and 348 grant this court jurisdiction to review EPA's denial. Because petitioners failed to comply with procedural prerequisites for review under § 348(g) and because we find no appealable order for purposes of § 346a(i), we dismiss for want of jurisdiction.

BACKGROUND

A. *Statutory Framework*

The Environmental Protection Agency (EPA or Agency) regulates pesticides under two separate statutes—the Federal Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. §§ 301-392, and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136-136y. Before a pesticide may be sold or distributed in the United States, it must be registered

by EPA under FIFRA. A pesticide may be registered only if it does not cause "unreasonable adverse effects" on human health or the environment, a standard that is applied by weighing the benefits of a pesticide against its risks. 7 U.S.C. §§ 136a, 136(bb).

Under the FDCA, no residue of a pesticide not generally recognized as safe may be present on a raw agricultural commodity unless the Agency has established a "tolerance" or an exemption from the requirement of a tolerance. 21 U.S.C. § 346a(a). A tolerance is the maximum allowable amount of pesticide that may remain in or on a commodity. Under section 346a(b), the Administrator must issue a regulation establishing a tolerance for the pesticide "to the extent necessary to protect the public health." In establishing a tolerance, the Administrator is to "give appropriate consideration, among other relevant factors, [ ] to the necessity for the production of an adequate, wholesome, and economical food supply." *Id.* The Administrator may set the tolerance at zero if the available scientific data do not justify the establishment of a greater tolerance. *Id.*

In addition to establishing tolerances for raw products, the Agency may set tolerances for pesticide residues in processed foods. 21 U.S.C. § 348(d).[1] Absent such a tolerance, a processed food bearing residues at levels in excess of that authorized in the raw product is considered "adulterated" and prohibited in interstate commerce. 21 U.S.C. § 342(a)(2)(C). Section 348 also contains a provision known as the "Delaney clause," which dictates that "no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal . . . ." 21 U.S.C. § 348(c)(3)(A).

[1]Under the Reorganization Plan that established EPA in 1970, the authority to set tolerances for pesticide chemicals under § 348 was transferred from the FDA to the EPA. Reorg. Plan No. 3 of 1970, § 2(a)(4), (a)(8)(i), 40 C.F.R. pt. 1 (1970), *reprinted in* 5 U.S.C. app. at 1132 (1982).

Both section 346a and 348 permit persons outside the EPA to request the Agency to set a tolerance. Section 346a(e) provides:

> The Administrator may at any time, upon his own initiative or upon the request of any interested person, propose the issuance of a regulation establishing a tolerance for a pesticide chemical . . . .

If within 30 days of the publication of such a proposal, there has been no request for an advisory committee, the Administrator "may by order publish a regulation based upon the proposal[.]" *Id.*

Similarly, section 348 permits "any person" to file a petition proposing the issuance of a regulation prescribing, among other things, a tolerance level. 21 U.S.C. § 348(b). Thereafter, the Administrator must, by order, either establish a regulation or deny the petition. 21 U.S.C. § 348(c).

B. *Administrative Proceedings*

The pesticide at issue in this case is daminozide, a plant growth regulator the principal use of which is on apples. Daminozide is sold by respondent Uniroyal under the trademark name "Alar." First registered in 1963, it was approved for use on apples in 1968. Alar reduces crop losses and lowers harvesting costs by preventing the fruit from dropping off the trees prior to harvest. It also reduces many fruit disorders, increases fruit size, and enhances the firmness of the apples, enabling them to be stored and marketed throughout the year.

Unfortunately, there is also evidence to suggest that daminozide or its degradation product, unsymmetrical dimethylhydrazine (UDMH), may be an animal carcinogen. Five scientific studies conducted between 1973 and 1984 demonstrated with statistically significant results a correlation between ingestion of Alar and various types of tumors in

certain lab animals. Both the methodology and the results of these studies have been questioned, however, and the parties in this case disagree as to their significance.

The studies aroused sufficient concern at the EPA that in June 1984 the Agency stated that based on its review of the data, it had "concluded that daminozide and its UDMH hydrolosis product are oncogenic [tumor causing] in laboratory rats and mice." Guidance for the Interim Registration of Pesticide Products Containing Daminozide as the Active Ingredient at 12. UDMH was characterized as "a known animal oncogen." *Id.* at 5.

The next month, the agency initiated a "special review" to determine whether to publish a notice of intent to cancel Alar's registration. 49 Fed. Reg. 29,126 (July 18, 1984). EPA allowed Uniroyal 45 days to submit evidence, including any published or unpublished studies and analyses, and directed registrants "to notify EPA of any studies currently in progress." *Id.* at 29,140. Uniroyal provided extensive comments criticizing the validity of the studies of daminozide. Specifically, the company contended that the tests were conducted under unacceptable procedures that rendered the results unreliable, that some of the test animals were diseased, and that daminozide had been administered in amounts in excess of the maximum tolerated dose.

Despite Uniroyal's submissions, the Agency reaffirmed its earlier conclusions in a September 1985 report which found that "the tumor incidences are so consistently overwhelming that the experimental deficiencies were not considered fatal flaws." Review of the Audit Conducted by Uniroyal at 11 (September 11, 1985). Before formally initiating the process of canceling a registration, the Agency must submit all underlying data in support of its proposed action to the Scientific Advisory Panel (SAP). Accordingly, EPA drafted Position Document 2/3/4 (PD 2/3/4) concluding that the cancer risk to adults from Alar residues in foods lay between 1/100 and 1/

1000. PD 2/3/4 at II-48. Since infants may be exposed to 10 to 14 times more Alar than adults, the Agency found the cancer risk to babies commensurately greater. *Id.* at II-51. On the basis of these findings, EPA's Position Document announced it was "conducting an expedited cancellation for food uses of daminozide." *Id.*, Executive Summary at 3. The document and the supporting data were submitted to the SAP, and notice of a public SAP meeting was published. 50 Fed. Reg. 35,317 (Aug. 30, 1985).

The SAP held a one-day hearing on September 26, 1985. Uniroyal presented expert testimony that disagreed with EPA's proposed findings, and reiterated many of the positions it had presented to the Agency. It also argued that the test results were equivocal, and that it had commenced new rat and mouse feeding studies of daminozide that would be completed in 1988. The Agency responded by acknowledging flaws in the studies, but stated that, evaluated cumulatively, the studies supported the decision to cancel the registration.

On October 4, 1985, the SAP issued its written findings. It concluded that while the studies gave rise to some concern, the data were "inadequate to perform a qualitative risk assessment." Such an assessment would have to wait until "adequate data become available." The panel criticized the manner in which the quantitative risk assessments were performed in the draft position documents, stating that it had reservations over the "technical soundness" of the risk assessments. At about the same time, EPA referred its draft position document to the Secretary of Agriculture, as required by 7 U.S.C. § 136d(b). The Department (USDA) responded that EPA had underestimated the benefits of daminozide in its preliminary assessment.

After considering the SAP conclusions, the USDA comments, and the scientists' reports, the Agency announced on January 22, 1986 that it would not at that time issue a notice of intent to cancel the registrations of daminozide and that it

would reserve a final decision on the special review until reliable data were obtained. EPA Press Release. EPA required Uniroyal to conduct new studies on the toxicity and metabolism of daminozide and UDMH. No one challenged the Agency's decision not to cancel the registrations.

On April 16, 1986, EPA issued a proposed rule under 21 U.S.C. § 346a(e) to reduce the daminozide tolerance on apples from 30 to 20 parts per million (ppm). 51 Fed. Reg. 12,889 (April 16, 1986). Petitioner Natural Resources Defense Council (NRDC), several other environmental groups, two trade associations and a number of states submitted comments.

On July 1, 1986, while EPA's proposed rule was still pending, several of the petitioners in this case filed a petition with the EPA under 21 U.S.C. §§ 346a and 348 to revoke the tolerance for daminozide. Petition for Establishment of Zero Tolerances. The petition relied on the studies the Agency had analyzed in PD 2/3/4. Uniroyal submitted comments opposing petitioners' request and supporting the proposed tolerance reduction to 20 ppm.

EPA denied the petition on January 6, 1987. It cited its finding that the available data were not adequate to classify daminozide or UDMH as carcinogens. The Agency stated that regulation of pesticides must proceed in a coordinated manner under both FIFRA and the FDCA. It claimed that when the criteria for cancellation under FIFRA are not met and there is a need for further data, FIFRA requires the EPA to afford registrants "sufficient time" to obtain the additional information. 7 U.S.C. § 136a(c)(2)(A), (B). Citing the studies that Uniroyal had agreed to conduct, the EPA said "[u]ntil these studies are received, the Agency cannot reach any definitive conclusions about the long-term risks posed by the use of daminozide. Based on available data, however, the Agency has concluded that any risk posed to consumers during the time period required for data generation is small . . . ."

Ten days later, on January 16, 1987, the Agency published a final rule lowering the tolerance for daminozide residues in apples from 30 ppm to 20 ppm until July 31, 1987. 52 Fed. Reg. 1909 (Jan. 16, 1987). The Agency stressed that the use of an interim apple tolerance would permit it to reassess daminozide in light of new data. No one filed objections or requested a hearing on the rule.[2]

On March 9, 1987, sixty days after the denial of their petition, petitioners brought suit in this court, seeking review of the denial of their petition for rulemaking.

JURISDICTION

Both EPA and Uniroyal contend that we lack jurisdiction over this petition. Before turning to an analysis of their arguments, we must resolve some ambiguity as to what precisely is being appealed. The Agency contends that petitioners have appealed both the January 6, 1987 denial of their petition and the final ruling of January 16, 1987 to lower the tolerance to 20 ppm. Brief for Respondent at 20.

[2]Subsequently, on March 3, 1987, EPA issued proposed rules to eliminate tolerances for daminozide residues in foods for which the pesticide was no longer registered under FIFRA. The Agency also proposed to lower the tolerance on raw tomatoes from 40 ppm to 0.5 ppm, the tolerance on concentrated tomatoes from 32 ppm to 3 ppm, and the tolerance on tomato pomace (used in animal feed) from 600 ppm to 10 ppm. 52 Fed. Reg. 6344, 6348 (March 3, 1987). In June of that year, Uniroyal filed a petition under section 346a(d)(1) requesting an extension of the 20 ppm tolerance. EPA responded by publishing a notice that invited public comments, but none were received. 52 Fed. Reg. 23,077 (June 17, 1987). EPA decided on the basis of the studies submitted by Uniroyal that a continuance of the 20 ppm level was needed and would be adequate to protect the public health in the short term.

On July 29, 1987, EPA issued a final rule extending the 20 ppm tolerance through January 31, 1989, at which time Agency experts will have received and reviewed the additional data earlier requested. 52 Fed. Reg. 28,256.

This conflicts with what petitioners claim they are appealing. In their reply brief, they expressly disavow that they are "seeking review of an EPA decision establishing a tolerance, . . . in fact[,] petitioners seek review of the agency's denial of their Petition to initiate proceedings to revoke a tolerance, as is clear from the petition for review and from the jurisdictional statement in their brief." Reply Brief at 10. Moreover, their claim of timeliness rests on the ground that "EPA denied the petition on January 6, 1987, and petitioners filed this petition for review in this Court on March 9, 1987, which was the final business day of the 60-day period[.]" Brief of Petitioner at 4-5. Petitioners confirmed at oral argument that they seek review only of the denial of their petition. They maintain that we have jurisdiction over the petition denial under both 21 U.S.C. §§ 346a(i) and 348(g). Respondent-intervenor Uniroyal responds that neither section grants this court jurisdiction over discretionary denial of a petition to revoke a tolerance. We review these two provisions in turn.

1. Section 348

[1] As noted, 21 U.S.C. § 348(b) permits any person to file a petition proposing regulations for the use of food additives. Under § 348(c), the Administrator must either "by order establish a regulation (whether or not in accord with that proposed by the petitioner)," § 348(c)(1)(A), or "by order deny the petition, and . . . notify the petitioner of such order and of the reasons for such action." § 348(c)(1)(B).

[2] Within 30 days after publication of an order pursuant to subsection (c), "any person adversely affected by such an order may file objections thereto with the [Administrator] specifying the reasons for the objections and requesting a public hearing upon such objections." 21 U.S.C. § 348(f)(1). After a hearing, the Administrator must "by order act upon such objections" based upon a fair evaluation of the entire record at the hearing. 21 U.S.C. § 348(f)(2).

[3] Should an "actual controversy" arise "as to the validity of any order issued under subsection (f)," section 348(g) permits direct review of such an order in the court of appeals. To obtain review, any person "who will be adversely affected" must file a petition within 60 days of the order. 21 U.S.C. § 348(g)(1).

Petitioners read subsection (f) as permitting but not requiring aggrieved parties to file objections. This argument is correct as far as it goes—that is, a party adversely affected by an order under subsections (c) or (d) is under no obligation to file objections pursuant to subsection (f). If the party seeks to invoke judicial review under § 348(g), however, objection under § 348(f) is a prerequisite. By its plain terms, section 348(g) permits judicial review in this court only of orders issued under subsection (f). Subsection (f) permits persons adversely affected by the denial of a petition to file objections with the Administrator and seek a hearing. The jurisdiction of the court encompasses orders pertaining to administrative objections, *not* the grant or denial of the petition in the first instance. Had Congress intended to permit direct review of petition denials, it would have conferred jurisdiction over orders issued under subsection (c). Subsection (f) would have been superfluous.

[4] After their petition was denied, petitioners did not file objections with the Administrator under subsection (f). Since more than 30 days have now elapsed, they cannot allege jurisdiction under section 348(g).

2. Section 346a

Petitioners assert an alternative ground for jurisdiction in 21 U.S.C. § 346a(i)(1). They advance the argument that the Agency's denial of their petition constituted an appealable order, but submit virtually no relevant authority to sustain this contention. Indeed, our independent review of the lan-

guage, context and legislative history of the FDCA leads us to the opposite conclusion.

[5] Section 346a(i)(1) grants the courts of appeals jurisdiction to review "the validity of any order under [§ 346a(e)]." Section 346a(e) provides that upon the request of an interested person, the Administrator "may at any time . . . propose the issuance of a regulation establishing a tolerance[.]" By its permissive terms, § 346a(e) plainly accords the Administrator considerable latitude in determining whether to grant a request to propose a tolerance. This discretion contrasts markedly with the provisions of subsections (b), (c) and (d), each of which states that the Administrator "shall" take prescribed action pertaining to promulgating regulations. So deferential is subsection (e) that the Administrator is not only free to deny the requested regulation, she need not even propose it. *See* 40 C.F.R. § 180.29(a) (1987).

[6] Furthermore, the plain wording of § 346a(e) denominates as an "order" only one act of the Administrator: the publishing of a regulation. Unlike § 348(f), it does not characterize the denial of a petition as an "order." As discussed above, subsection (i) authorizes review only of *orders*, not of every act by which a petitioner is aggrieved. Were the Administrator required upon request to propose a regulation, it might plausibly be argued that the denial of a petition for rulemaking in light of new evidence was tantamount to the issuance of a new regulation, and thus an appealable order. Under § 346a(e), however, the only mandatory requirements imposed on the Administrator are not triggered unless the Administrator, in her discretion, first elects to grant a petition for proposing a regulation. If she chooses instead to *deny* a petition, § 346a(e) requires nothing of her.

Our view finds further support in the legislative history. In enacting subsection (i), Congress stated that it provides for appellate court review of orders "*establishing* tolerance or exemption regulations . . . . Review is available in any case of

'actual controversy' to any person who will be adversely affected by tolerance or exemption regulations[.]" S. Rep. No. 1635, 83d Cong., 2d Sess., *reprinted in* 1954 U.S. Code Cong. & Admin. News 2626, 2635 (emphasis added).

[7] Nor is the denial of a rulemaking petition within the meaning of "order" as that term is defined in the Administrative Procedure Act (APA). The chapter of the APA governing judicial review defines an order as "a final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency *in a matter other than rule making* but including licensing." 5 U.S.C. § 551(6), *incorporated in* 5 U.S.C. § 701(b)(2) (emphasis added). As section 346a(e) governs rulemaking, the APA definitions do not apply, and we must look to the statute itself for what Congress intended.

Petitioners claim that *National Coalition Against the Misuse of Pesticides v. Thomas,* 809 F.2d 875 (D.C. Cir. 1987), supports a finding of jurisdiction under section 346a(i). *National Coalition* is inapposite, however, because in that case the petitioners were appealing from the issuance of a regulation, not from the denial of a petition to initiate rulemaking. On February 14, 1986, the EPA published a final regulation in the Federal Register setting a tolerance level for ethylene dibromide. *Id.* at 878. The same day, petitioners filed for review in the D.C. Circuit under section 346a(i). *National Coalition* held that they could proceed directly to judicial review under subsection (i) without first pursuing the permissive administrative review of subsection (d)(5). *Id.* at 879.

The court found it had jurisdiction because the action appealed from—the promulgation of a regulation—was a reviewable order under the express terms of the statute. The court observed that since "the applicable statutory provisions [21 U.S.C. §§ 346a(e), (i)] by their terms permit review of such orders, conducting review at this stage does not appear to thwart Congressional purposes by encouraging 'deliberate

flouting of administrative processes,' a primary concern underlying the exhaustion doctrine." *Id.*

The absence of a final regulation distinguishes the case before us from *National Coalition*. Here, though they could have, petitioners elected not to object to or to appeal from the issuance of the final regulation. Indeed, their petition was both filed and denied while the proposed regulation on daminozide tolerances remained open for comment. On these facts, not only does *National Coalition* fail to reinforce their argument; it affirmatively undermines it.

[8] Were we to review the petition's denial, we would encourage the "deliberate flouting" against which *National Coalition* warned. Congress's "primary purpose" in enacting the provisions at issue was "to assure greater protection of the public health by improving, simplifying, and speeding up the procedure . . . for regulating the amount of residue which may remain" on commodities. S. Rep. No. 1635, *reprinted in* 1954 U.S. Code Cong. & Admin. News at 2627. Granting review of a denial under § 346a(e) would advance none of these goals, least of all simplicity. If parties were free simply to file petitions, await their denial, and then be assured of jurisdiction in the courts of appeals, there would be little incentive to comply with the procedural provisions of the FDCA that require direct appeals from a regulation to be made within the statutory time period. EPA could conceivably be forced to appear continually in appellate courts defending regulations long established that parties failed to contest at the time of their promulgation. If Congress had intended such a result, it is unlikely it would have prescribed a fixed deadline for appeals from regulations.

Petitioners' failure to pursue any of the avenues by which they *could* ultimately have obtained judicial review is perplexing, particularly in light of the fact that a regulation governing precisely the issue of concern to them was adopted only ten days after their petition was denied and *before* they

filed this appeal. The regulation lowering the daminozide tolerance to 20 ppm took effect on January 16, 1987. Under § 346a(d)(5), petitioners had 30 days from that date to file objections to the new regulations. Such objections, if supported by "reasonable grounds," would have triggered a host of procedures, including a public hearing at which petitioners could have made their evidence part of the record. *See* 40 C.F.R. § 180.13 (1987). After hearing and considering their objections and evidence, the Administrator would have promulgated a final regulation, reviewable in this court under § 346a(i)(1).

Petitioners also could have filed objections to their own petition's denial for 30 days following its denial pursuant to § 348(f). A timely filed objection under that section, as under § 346a(d)(5), obligates the Administrator to hold a hearing and issue an order based on the record made at the hearing. Had petitioners exercised this option and still been dissatisfied with the outcome, they could then have sought review in this court under the provisions of § 348(g)(1).[3]

Congress did not condition our jurisdiction over petition denials on compliance with the FDCA's procedures merely as a matter of empty formalism. Rather, section 348(f) performs the critical function of ensuring that a factual record is made before the Agency and reviewed by the Agency before resort to the court of appeals. By ignoring the statute's prescribed procedures and appealing directly to this court, petitioners bypassed the important intermediate step of objecting and requesting a hearing before the Agency. Were we to attempt to analyze the record in light of petitioners' concerns, we would in essence have to perform work the Agency, with its expertise, is far better qualified to do. The purpose of provi-

[3]Alternatively, petitioners could have avoided further Agency proceedings by simply appealing from the January 16, 1987 regulation in a timely fashion. Under *National Coalition* and the clear terms of § 346a(e), the promulgation of a regulation is a reviewable order.

sions such as § 348(f) is to bring the Agency's experience to bear on a contested question in the framework of a hearing, where contrasting views can be heard and evaluated by the Agency. While it is true that the Administrator considered petitioners' evidence before denying their request, the lack of a hearing and fully developed record deprives this court of the full benefit of the Agency's expertise.

We are aware that under other statutes, a decision not to pursue proposed rulemaking has been held judicially reviewable. *See, e.g., Natural Resources Defense Council v. Securities and Exchange Com'n,* 606 F.2d 1031 (D.C. Cir. 1979); *NRDC v. Nuclear Regulatory Com'n,* 666 F.2d 595 (D.C. Cir. 1981)(under Hobbs Act, 28 U.S.C. § 2342, court of appeals may review denial of rulemaking petition which challenges regulations on ground of substantive invalidity). None of these cases, however, involved the FDCA. Nor did the statutes that were at issue employ analogous language in respect to their grants of jurisdiction to that contained in the FDCA. The provision at issue in *NRDC v. NRC,* for example, defines as reviewable any order in "*any* proceeding for the issuance *or modification* of rules and regulations dealing with the activities of [NRC] licensees." 42 U.S.C. § 2239 (emphasis added). This broad language embraces a far more extensive range of reviewable actions than the limited grant of jurisdiction under 21 U.S.C. § 346a(i) to review orders under subsections (d)(5), (e) and (1). As the D.C. Circuit has noted, the FDCA

> contains no single, overarching provision governing judicial review. Instead, discrete agency actions are subject to specialized review provisions. See, e.g., . . . § 371(f) (review by court of appeals of orders issued pursuant to provisions enumerated in § 371(e)).[4] Agency actions taken under sections

[4]21 U.S.C. § 371(f) states: "In a case of actual controversy as to the validity of any order under subsection (e) of this section, any person who will be adversely affected by such order [may] file a petition with the United States court of appeals . . . for a judicial review of such order." This language closely tracks that of section 346a(i), although section 371(e) imposes affirmative duties on the Administrator, whereas section 346a(e) does not.

> silent in this respect are directly reviewable in a district court under some appropriate head of its jurisdiction, for courts of appeals have only such jurisdiction as Congress has chosen to confer upon them.

Cutler v. Hayes, 818 F.2d 879, 887 n.61 (D.C. Cir. 1987). Since jurisdiction in the case before us is predicated on a statute significantly more restrictive than those under which the denial of rulemaking has been found reviewable, we find those cases of little utility.

For the same reason, petitioners' reliance on *Florida Power and Light Co. v. Lorion,* 470 U.S. 729 (1985), is misplaced. Petitioners read *Florida Power* as a general affirmation that any agency's denial of a petition is a reviewable order. Yet in that case the Court faced the question of whether the denial of a petition could be reviewed directly in the court of appeals under 42 U.S.C. § 2239(b) and the Hobbs Act—the same statutes that were at issue in *NRDC v. NRC.* Its holding depended on its lengthy exegesis of those specific statutes; nowhere did the Court intimate that it was ruling as a matter of general administrative procedure. Since jurisdiction in these cases is wholly a creature of statute, we are not at liberty simply to apply the Court's reading of one statute to a separate, dissimilar statute.

In the FDCA, Congress constructed an elaborate yet consistent administrative design for the proposal, consideration, promulgation and review of regulations. The Act provides a number of well-defined avenues for participation by members of the public and review by appellate courts. These provisions permit the maximum citizen input consistent with the Agency's need for consistency and finality. Section 346a(e) states only that the Administrator may propose the issuance of a regulation upon the request of an interested person. She is not required to publish the proposal, hold a hearing, or publish her reasons should she elect to deny a petition. Short of

language expressly precluding any review, Congress could hardly have drafted a provision more deferential to the Administrator.

The statutory goals would not be advanced by appellate court review of the petition in this case. Petitioners filed their petition while a proposed regulation on its very subject matter was open for comment. When their petition was denied and the Agency's regulation adopted, they chose not to object to the new regulation or to the denial of their petition, nor to appeal from the regulation. Under petitioners' approach, an aggrieved party, at any time, could file a petition requesting rule-making, await its denial, and then obtain automatic review in the court of appeals. Nothing could be less conducive to finality.

We dismiss for lack of jurisdiction.

DISMISSED.

BEFORE THE UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

In re: Pesticide Tolerances for Daminozide	Petition for Establishment of Zero Tolerances

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Executive Summary

This petition formally requests that the Environmental Protection Agency amend existing food tolerances for the pesticide daminozide and reestablish the tolerances at zero. The petition is filed on behalf of the Natural Resources Defense Council, Public Citizen, the State of New York, the Maine Department of Human Services, and several pediatricians and young children. The petition charges that daminozide and its contaminant/breakdown product, UDMH, are potent carcinogens and that existing food tolerances are inadequate to protect the public health. The petition emphasizes that infants and young children are particularly at risk because they consume significant amounts of apple products, which may contain substantial levels of daminozide and UDMH.

Daminozide (brand name "Alar") is a plant growth regulator registered for use on apples, peanuts, and other fruits and vegetables. Tolerances were first established in 1968. Five separate studies conducted between 1973 and 1984 demonstrated that daminozide and UDMH (unsymmetrical dimethylhydrazine) are animal carcinogens. UDMH is formed upon heating or processing food containing daminozide residues. The studies revealed that daminozide and UDMH cause cancer in multiple strains and species of animals, in multiple experiments through different routes of administration, and to an unusual degree in numerous sites. For these reasons, EPA concluded that the chemicals are "probable human carcinogens" and proposed in September 1985 to cancel daminozide's use. This proposal was subsequently withdrawn.

Based on these health risks the State of Massachusetts recently issued regulatory measures that would significantly reduce and eventually eliminate daminozide residues in apple

products and all infant and baby foods. Similarly, the State of Maine announced a proposed rule to prohibit daminozide residues in all baby foods and heat-processed foods effective October 1, 1986. While EPA has proposed a reduction in the daminozide tolerance for apples from 30 p.p.m. to 20 p.p.m., this proposal is clearly not adequate to protect the public health.

Under the Federal Food, Drug and Cosmetic Act, daminozide's registrant — Uniroyal — bears the affirmative burden of demonstrating the safety of existing tolerance levels. In light of the strong evidence of carcinogenicity, and particularly given the increased risks to infants and young children, this burden has not, and cannot, be met. Accordingly, petitioners request immediate establishment of zero tolerances for daminozide, which is the only level that can be demonstrated to be safe.

INTRODUCTION

1. This is a formal petition, pursuant to 40 C.F.R. § 180.32 (1985) and 21 C.F.R. § 171.130 (1985), requesting that the Environmental Protection Agency (EPA) immediately amend the existing tolerances for the pesticide daminozide (marketed under the brand name "Alar") and reestablish the tolerances at zero. This petition is submitted on behalf of the Natural Resources Defense Council (NRDC); Public Citizen; the State of New York; the State of Maine, Department of Human Services; Philip J. Landrigan, M.D.; Alan J. Finley, M.D.; Noah and Naomi Beyeler; and Benjamin O. Purdon. Petitioners and their members and citizens are regularly exposed to daminozide and to its contaminant and breakdown byproduct, UDMH (unsymmetrical 1, 1- dimethylhydrazine), in the form of residues in raw and processed foods including apples, apple juice and apple sauce, peanuts, and a host of other fruits and vegetables. This request is

based on reasonable grounds in that significant new studies conducted since the establishment of the original tolerances in 1968 demonstrate that daminozide and UDMH are probable human carcinogens. The existing tolerances for daminozide allow residues in raw commodities at levels of 30 p.p.m. and higher, and in processed foods at up to 320 p.p.m.. *See* 40 C.F.R. 180.246 (1985); 21 C.F.R. § 193.410 (1985). As demonstrated below, these tolerances are clearly inadequate to protect the public health. Accordingly, petitioners hereby request that the agency reestablish the daminozide tolerances at zero, which is the only level that can de demonstrated to be safe at this time.

PETITIONERS

2. Petitioners include several infants and children, an environmental and consumer organization, the State of New York, the State of Maine Department of Human Services and pediatricians with a substantial interest in reducing or eliminating daminozide residues in food. Petitioner organizations have many thousands of members who are regularly exposed to daminozide through residues on apples, apple products, and numerous other fruits and vegetables. In addition, petitioners include infants and young children who consume a substantial amount of apples and apple products and who are therefore exposed to daminozide at unusually high levels.

3. Petitioner NRDC is a non-profit, environmental organization with approximately 62,000 members and contributors nationwide. NRDC has a longstanding interest in improving EPA's regulation of pesticides and in ensuring that pesticide residue levels in food are restricted in order to protect the public health. NRDC submitted comments supporting the agency's initiation of special review for daminozide and has consistently urged the

agency to establish a zero tolerance for daminozide in order to protect the public health. *See e.g.*, Letter from NRDC to Lee M. Thomas, Re: Daminozide (Alar) (January 22, 1986); NRDC, Comments on the Proposed Rule, Pesticide Tolerance for Daminozide (May 29, 1986). In addition, we have exhaustively analyzed EPA's regulation of pesticide residues in food, and have prepared detailed reports containing numerous recommendations for improving that process. *See* NRDC, *Pesticides in Food: What the Public Needs to Know* (1984), and NRDC, *Pesticide Reregistration: An Evaluation of EPA's Progress* (1986).

4. Petitioner Public Citizen is a non-profit public interest organization supported by annual contributions from approximately 60,000 members throughout the United States. Since 1971, the Public Citizen Health Research Group has engaged in research and advocacy to promote safe food and specifically to prohibit carcinogens from entering the food supply.

5. Petitioner State of New York as a body politic and a sovereign entity brings this petition on behalf of itself and as parens patriae, trustee, guardian and representative on behalf of all residents and citizens of the State of New York. New York has a population in excess of sixteen million people and is a major producer and consumer of agricultural commodities including apples and apple products. Although the State has the authority to regulate any deleterious substance, including daminozide, which may be present on food products produced, sold and/or consumed within the State, it is New York's position that from an economic and practical point of view the regulation of daminozide would be most efficient if implemented on a national basis.

6. Petitioner State of Maine Department of Human Services

originated in 1885 with the creation of the State Board of Health, appointed by the governor, to protect the interests of the health and life of the citizens of Maine. Michael R. Petit, the current Commissioner of the Department, signs this petition in consideration of the health of the 1.2 million citizens of Maine. The Maine Bureau of Health, a division of the Maine Department of Human Services, believes that tolerance levels should reflect the results of the toxicological data and that the appropriate tolerance for daminozide should be zero.

7. Petitioners Noah D. Beyeler, Naomi S. Beyeler, and Benjamin O. Purdon are children residing in Oakland, California, who regularly consume apples, apple products, and other foods that may contain daminozide and UDMH. Noah is one year old; Naomi is four years old; and Benjamin is nineteen months old.

8. Petitioner Philip J. Landrigan, M.D., is a pediatrician, Chairman of the Committee on Environmental Hazards, American Academy of Pediatrics, and Director, Division of Environmental and Occupational Medicine, Mount Sinai School of Medicine.

9. Petitioner Alan J. Finley, M.D., is a pediatrician in private practice in Martinez, California.

10. In sum, the individual petitioners, the citizens and residents of New York and Maine, the patients of the pediatrician petitioners and the members of the organizational petitioners are regularly exposed to daminozide and UDMH and have a "substantial interest" in amending the daminozide tolerances in order to reduce that exposure. *See* 40 C.F.R. § 180.32(b) (1985).

NEW STUDIES DEMONSTRATE THAT DAMINOZIDE AND UDMH ARE CARCINOGENIC AND PROVIDE REASONABLE GROUNDS FOR AMENDING EXISTING TOLERANCES

11. Daminozide is a plant growth regulator registered for use on apples, peanuts and other fruits and vegetables. A tolerance allowing residues of daminozide in apples was set in 1968, and tolerances for other foods have been established subsequently. As described below, EPA initiated a "special review" for daminozide in 1984 due to oncogenicity concerns. EPA proposed in September 1985 to cancel daminozide's use, but then withdrew this proposal after a hearing before the Scientific Advisory Panel. On April 16, 1986, the agency proposed to reduce daminozide apple tolerance from 30 p.p.m. to 20 p.p.m., but no final action has been taken at this time.

12. Studies prepared after the initial establishment of the daminozide tolerances show that both daminozide and UDMH are animal carcinogens and probable human carcinogens. The agency's own analysis of these studies, contained in the daminozide Registration Standard, the Position Document 1 (PD-1) relating to the special review, and in other documents which are discussed below, unambiguously supports this conclusion. These studies and the agency's underlying analyses create a substantial question of safety regarding the existing daminozide tolerance levels. Because daminozide's registrant, Uniroyal, has a continuing burden under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 346a, of demonstrating the safety of existing tolerance levels, and because the agency's analysis of the new studies demonstrates that this burden under federal law has not and indeed cannot be met, the agency must immediately amend and reestablish the tolerance levels at zero.

13. This request is based, *inter alia*, on the following studies:

(a) Toth, B., 1973. 1,1-Dimethylhydrazine (unsymmetrical) carcinogenesis in mice. Light microscopic and ultrastructural studies on neoplastic blood vessels. Journal of the National Cancer Institute 50: 181-187.

(b) Toth, B., *et al.*, 1977. Induction of tumors in mice with the herbicide succinic acid 2,2- dimethylhydrazide. Cancer Research 37:3497-3500.

(c) Toth, B., 1977. The large bowel carcinogenic effects of hydrazines and related compounds occurring in nature and in the environment. Cancer 40: 2427- 2431.

(d) National Cancer Institute, 1978. Bioassay of Daminozide for Possible Carcinogenicity. United States Department of Health, Education and Welfare, Public Health Service. (NCI Carcinogenesis Technical Report Series No. 83; DHEW Publication No. NIH 78-1333).

(e) Haun, C. C. *et al.*, 1984. Chronic Inhalation Toxicity of Unsymmetrical Dimethylhydrazine; Oncogenic Effects. Air Force Aerospace Medical Research Laboratory, Wright-Patterson Air Force Base, Ohio.

14. These five studies demonstrate that both daminozide and UDMH are carcinogenic. Two studies have been conducted on daminozide since the establishment of the tolerances. Daminozide was administered to mice both in the diet (NCI, 1978) and in drinking water (Toth *et al.*, 1977) and to rats in their feed (NCI, 1978). These studies have produced rare uterine carcinomas in rats (NCI, 1978) and tumors in the lung (NCI, 1978; Toth *et al.*, 1977), liver (NCI, 1978), blood vessels (Toth *et al.*, 1977) and

kidneys (Toth *et al.*, 1977) in mice. Moreover, three studies have been conducted on UDMH since the establishment of the daminozide tolerances. UDMH was administered in drinking water to mice (Toth, 1973) and hamsters (Toth, 1977), and to dogs, hamsters, mice and rats via inhalation (Haun *et al.*, 1984). These studies have induced blood vessel (Toth, 1973; Haun *et al.*, 1984), kidney (Toth, 1973) and nasal tumors (Haun *et al.*, 1984) in mice. Pancreatic tumors were induced in rats (Haun *et al.*, 1984) and cecum tumors in hamsters (Toth, 1977). Additionally, two studies conducted in 1967 demonstrated that UDMH administration produced tumors in the test animals. Druckery, H., *et al.*, 1967. Organotrope carcinogene Wirkungen bei 65 verschiedenen N-Nitroso-Verbindungen an BD ratten. Z. Krebsforsch 69:103 (Cited in IARC, 1974). Roe, F.J.C. *et al.*, 1967. Carcinogenicity of hydrazine and 1,1-dimethylhydrazine for mouse lung. Nature 216 (5113):375-76.

15. This request is also based on other carcinogenicity and toxicology studies that are cited in the Registration Standard and other agency documents discussed below. Petitioners request that these studies be made part of the record in this proceeding. Because the agency has copies of these studies, additional copies have not been submitted with this petition.

16. EPA scientists have known since at least 1977 that daminozide and UDMH are carcinogenic. In an agency memorandum to Drs. Rogoff and Paynter, Toxicology Branch, from Sin-Lam Chan, Ph.D., dated August 15, 1977, Dr. Chan described the positive carcinogenicity results reported by Toth *et al.* (1977). Dr. Chan concluded that "[t]he results from the above study by Drs. B. Toth and A. Tompa should place Alar as an RPAR candidate. I would like to draw your attention to the large number of tolerances established under daminozide." (RPAR refers to "Rebuttable Presumption Against Registration," now known as

"special review," which is the agency's intensive process for determining whether to cancel or restrict particularly hazardous pesticides.) Three years later, in correspondence to Uniroyal Chemical Company and Aceto Chemical Company, Inc. dated October 27, 1980, and October 23, 1980, respectively, EPA privately notified registrants that daminozide products were "to be reviewed as possible candidates for issuance of a Rebuttable Presumption Against Registration." This determination was based on two studies that "showed daminozide to be a carcinogen in mice." In an agency memorandum to Robert Taylor, Registration Division, from Salvatore F. Biscardi dated July 10, 1981, the EPA scientist cites draft agency documents which state that daminozide poses an oncogenic risk in excess of the acceptable level set forth in agency policy. A later memorandum from Larry Anderson, EPA toxicologist, to Jeff Kempter, Chief, Chemical Review Branch, dated December 14, 1981, discusses the studies and concludes simply that the documents "show carcinogenic activity for daminozide and [UDMH]." In that memorandum, UDMH is referred to as "a demonstrated carcinogen." (Petitioners hereby request that these and all other EPA documents cited in this petition be included in the record for this proceeding.)

17. In the "Pesticide Registration Standard and Guidance Document" for daminozide (June 1984), the agency publicly recognized that daminozide and UDMH are carcinogenic. As stated in the Registration Standard, "the agency has completed its review of the data base for daminozide and has concluded that daminozide and its UDMH hydrolysis product are oncogenic in laboratory rats and mice." UDMH is referred to as "a known animal oncogen." In addition, EPA concluded that "dietary risk estimates for daminozide and UDMH indicate that an unacceptable risk may exist from consumption of raw and processed agricultural commodities treated with daminozide," and stated

that it was "particularly concerned" about risks to young children.

18. Based on the serious health concerns unambiguously set forth in the Registration Standard, EPA initiated a "special review" for daminozide in 1984. *See* 49 Fed. Reg. 29136 (July 18, 1984). The notice reiterates and reconfirms the agency's "conclusion that daminozide and UDMH cause oncogenic effects in laboratory animals and that dietary exposure and oncogenic risk are high." This conclusion was based on the agency's analysis of the various cancer studies, which, according to the agency, demonstrate "that daminozide is oncogenic in laboratory rats and mice, and UDMH...is oncogenic in laboratory mice and hamsters. Moreover, some tumors are formed at uncommon sites." The notice also states that, in addition to causing cancer in laboratory animals, UDMH "has demonstrated mutagenic activity in both the presence and absence of metabolic activation." Mutagenicity is a useful biological indicator of cancer-causing potential.

19. In January 1985, five EPA scientists conducted a formal audit of the two cancer studies published by B. Toth that served, in part, as the basis for the agency's conclusions regarding daminozide's oncogenicity. The auditors concluded that daminozide "is a clear carcinogen in that it induces a highly significant increase in the incidence of blood-vascular tumors which are normally found at a very low incidence in Swiss mice." EPA, "Report of the Audits of the Studies on the Carcinogenic Potential of Succinic Acid 2, 2-Dimethylhydrazide (Daminozide) and 1, 1-Dimethylhydrazine in Swiss Mice," p. 8 (April 22, 1985). Furthermore, the EPA scientists determined that the overall safety of daminozide "is apt to be significantly less" than estimated by the Toth studies, because the studies focused solely on neoplastic (i.e., cancerous) lesions and ignored other lesions.

Id. One of the auditors, Dr. Adrian Gross, specifically noted that the toxicity of daminozide "would probably have been determined to be higher" had the study been carried out pursuant to present laboratory practices. *Id.*, "General Comments With Respect to the Pathology Operations," p. 2.

20. At the request of EPA, an independent histopathologic review of the carcinogenicity study on Swiss mice that were administered UDMH in drinking water was conducted. Goodman, D., PATHCO, Inc., "Review of Blood Vessel Neoplasms and Neoplasms of Lung, Kidney, and Liver in Swiss Mice Administered 1, 1- Dimethylhydrazine in Drinking Water" (August 29, 1985). The audit corroborated the original study's finding that UDMH administration led to increased incidences of multiple types of tumors at multiple sites in both sexes of mice. The scientist conducting the audit summarized her conclusions as follows: "1, 1-dimethylhydrazine is a carcinogen inducing hemangiosarcomas, primarily of the liver and alveolar/bronchiolar neoplasms of the lung in both sexes of Swiss mice, and renal tubular adenomas in males and possibly hepatocellular neoplasms in males." Letter from Dawn Goodman to James Plautz, Dynamac Corporation (August 22, 1985).

21. After reviewing the comments on the PD-1 and the results of its audit of the Toth studies, EPA issued a draft PD- 2/3/4 on September 12, 1985, which proposed expeditiously to cancel daminozide's use. This decision was based on the following central findings:

> [S]tudies have shown that both daminozide and its degradate and metabolite, [UDMH], are oncogenic in laboratory animals. Specifically, data indicate that administration of daminozide to laboratory animals has resulted in statistically and biologically significant oncogenic responses at

> multiple organ sites and multiple species and strains of animals. ... The daminozide metabolite, UDMH, is believed to be a very potent animal carcinogen and mutagen.

Executive Summary, p. 1.

22. Based on all available evidence, EPA concluded that daminozide should be classified as a "probable human carcinogen" under the EPA proposed cancer guidelines. PD-2/3/4 at II-29. This conclusion was compelled by the fact that daminozide satisfied not one, but *all* of the criteria set forth in EPA's proposed cancer guidelines. As stated in the PD-2/3/4:

> Thus, one strain of mouse showed an unequivocal oncogenic response (Toth), a second strain of mouse showed equivocal evidence at a high incidence and reduced lifespan in both sexes (NCI study) and the rat showed a compound related oncogenic response. According to the EPA proposed guidelines on carcinogen risk assessment this provides sufficient evidence that daminozide is carcinogenic in experimental animals, fulfilling *all* the following criteria. ["(a) in multiple species or strains; *or* (b) in multiple experiments (preferably with different routes of administration or using different dose levels); *or* (c) to an unusual degree with regard to incidence, site or type of tumor or age at onset."]

Id. at II-29 (emphasis in original). Similarly, based on identical findings, the agency concluded that UDMH was also a "probable human carcinogen." *Id.* at II-30.

23. The agency's conclusions regarding daminozide's oncogenicity were reiterated during the Scientific Advisory Panel (SAP) hearing on September 26, 1985. EPA scientist Dr.

Theodore Farber discussed the various daminozide and UDMH tests at length and concluded that both chemicals are oncogenic. Similarly, EPA's Paul Lapsley stated that "the weight of the evidence conclusion [regarding daminozide's oncogenicity] ... is compelling." Moreover, Mr. Lapsley stated the agency's view that "[w]e don't believe that there is going to be significant new data that would be developed and demonstrate that there is no oncogenic response from UDMH" or daminozide. (The SAP concluded that the studies "give rise to concern over the potential oncogenicity of daminozide" and "provide some evidence of [UDMH's) potential oncogenicity," but stated that the data were not adequate for risk assessment purposes.)

24. The oncogenicity of UDMH is further supported by analysis prepared by EPA's Office of Solid Waste, which intends to list UDMH as a hazardous waste because it is carcinogenic, mutagenic, and teratogenic. EPA, 40 CFR Parts 261 and 271, Hazardous Waste Management System: Identification and Listing of Hazardous Waste, Final Rule, p. 3 (undated internal agency document provided in response to NRDC's January 23, 1986 Freedom of Information Act (FOIA) request). In 1984 EPA proposed listing four wastes generated during production of UDMH as hazardous wastes under the Resource Conservation and Recovery Act. 49 Fed. Reg. 49556 (December 20, 1984). The hazardous constituent in these wastes is UDMH. In the internal agency document (cited above) that would serve as the final rule for listing UDMH, EPA responded to comments criticizing the UDMH carcinogenicity bioassay by stating that EPA's 1985 audit found the study to be valid. Moreover, scientists in EPA's Office of Research and Development reviewed the critical comments and concluded that the fundamental conclusions of EPA's risk assessment of UDMH were correct. Memorandum from Chris DaRosa, EPA, to C. Jenkins, re: Uniroyal, Inc. comments on 1, 1-dimethyl-hydrazine (October 10, 1985).

25. In the background document prepared for the UDMH Federal Register notice, EPA stated that "using criteria recently developed by EPA's Carcinogen Assessment Group (CAG), [U]DMH would be classified as a probable human carcinogen (class B2)." Non-Confidential Business Information, Listing Background Document 1;1-Dimenthylhydrazine (UDMH) Production from Carboxylic Acid Hydrazides, p. 3 (undated EPA document provided in response to NRDC's FOIA request). In Appendix A to this background document, EPA rebuts in careful detail comments challenging EPA's determination of oncogenicity for UDMH. In the attachments to an EPA memo regarding the characterizations of UDMH's oncogenicity by different EPA offices, it is noted that "OSW, ORD and OPTS scientists generally believe that available evidence is sufficient to qualitatively establish that UDMH is a carcinogen." Memorandum from Cate Jenkins, EPA, to May 15, 1986 Meeting Attendees, Subject: Summary of OSW's Attempted Revised Language to Finalize the UDMH Listings Without Contradicting OPP's Decision and Expanded History of Interaction Between OSW/OPP/ECAO/CAG/SAP Scientists, Attachment entitled UDMH History, Interactions Between OSW and OPTS (May 15, 1986).

26. These conclusions regarding daminozide's oncogenicity have been confirmed by other scientists and state officials, including the Commissioner of the Massachusetts Department of Public Health, the New York State Department of Health, and the Maine Department of Human Services. *See, e.g.*, Letter to Stephen Schatzow, Director, OPP, from Bailus Walker, Jr., Ph.D., Commissioner, Massachusetts Department of Public Health (January 16, 1986) (Exhibit 1) ("We feel that the existing toxicology data...show sufficient (at least qualitative) evidence that daminozide and UDMH are carcinogens and that exposure must be minimized (in the short term) and eliminated (in the long term)"); New York State Department of Health, Bureau of Toxic

Substance Assessment, *Qualitative Assessment of the Carcinogenicity of Daminozide and UDMH in Rodents* (January 27, 1986) (Exhibit 2) (After reviewing the studies in detail, the Department concludes that both daminozide and UDMH should be classified as "probable human carcinogens" under the EPA draft guidelines.); Letter to Nancy Ridley, Massachusetts Department of Public Health, from Nancy K. Kim, Ph.D., New York State Department of Health (January 27, 1986) (Exhibit 3) ("Based upon our review, the evidence presented by the different chronic bioassays supports a conclusion that daminozide and/or UDMH is carcinogenic in rodents."); Memorandum to Commissioner Bailus Walker, Department of Public Health, Commonwealth of Massachusetts, from Nancy Ridley, Director, Division of Food and Drugs (February 11, 1986) (Exhibit 4) (concluding that existing studies "clearly indicate" that both daminozide and UDMH are carcinogens); Maine Department of Human Services, Bureau of Health, *Carcinogenicity Risk Assessment for Daminozide and Unsymmetrical Dimethyl Hydrazine (UDMH)* (May 13, 1986) (Exhibit 5) (The Department thoroughly reviewed all available evidence on the carcinogenicity of daminozide and UDMH and concluded that daminozide and UDMH "are probable human carcinogens" and "may be potent carcinogens.").

27. Based on these health risks, the Commonwealth of Massachusetts recently issued regulatory measures that would significantly reduce, and eventually eliminate, daminozide residues in apple products and infant and baby foods. Action Levels for Poisonous or Deleterious Substances in Food, Mass. Admin. Code Tit. 105, § 515.000 (1986). As stated by the Massachusetts Department of Public Health, The Center for Health Promotion and Environmental Disease Prevention, in *Daminozide Carcinogenicity and Risk Assessment (Executive Summary)* (May 13, 1986) (Exhibit 6), "[a]nalyses of numerous carcinogenesis

bioassays and short-term data demonstrate unequivocally that daminozide is a carcinogen." *See also* Memorandum to Commissioner Bailus Walker, Department of Public Health, Commonwealth of Massachusetts, from Stephen Havas, M.D., Deputy Commissioner, Re: Final Daminozide Regulations, pp. 5-8 (May 13, 1986) (Exhibit 7). In addition, the State of Maine recently announced a proposed rule to prohibit daminozide residues in all baby foods and heat-processed foods effective October 1, 1986. State of Maine, Department of Agriculture, Notice of Agency Rulemaking Proposal, Daminozide/UDMH: Acceptable Residue Levels In Heat Processed Foods (May 28, 1986) (Exhibit 8). (Petitioners hereby request that the documents cited in this and the preceding paragraphs be included as part of the administrative record in this proceeding, and have included the documents in an exhibit to this petition for this purpose).

28. In sum, the foregoing studies, analyses, and other evidence demonstrate that both daminozide and UDMH are probable human carcinogens. EPA's analysis has repeatedly confirmed this fact. The studies show that daminozide and UDMH cause cancer in multiple strains and species of animals, in multiple experiments through different routes of administration, and to an unusual degree in numerous sites. Thus, the new studies clearly provide reasonable grounds for revising daminozide tolerances and reestablishing the tolerances at zero.

DAMINOZIDE AND UDMH EXPOSURE LEVELS AND DIETARY RISKS ARE HIGH, PARTICULARLY FOR INFANTS AND YOUNG CHILDREN

29. Exposure levels to daminozide and UDMH are very significant, creating an unacceptable dietary risk, particularly to infants and young children. Approximately 38 percent of the fresh market apple crop, 11 to 12 percent of the peanut crop, 15

to 30 percent of the cherry crop, and lesser percentages of other fruits and vegetables are treated with daminozide. PD 2/3/4, pp. III-9, III-16, III-17. Actual daminozide residue levels on raw produce have ranged from less than 1 pp, to 4.8 ppm. Residue levels of UDMH in processed foods have been particularly significant, because UDMH concentrates during processing. EPA's PD 2/3/4 estimated than an average of 1.4 and 3.3 percent of the daminozide residues in raw apples converted to UDMH in apple juice and sauce, respectively. Thus, infants and young children, who consume large amounts of apple juice, apple sauce, peanut butter, and other processed products, are by far at the highest risk from daminozide and UDMH dietary exposure.

30. EPA's Registration Standard for daminozide explicitly states that the "oncogenic dietary risk of daminozide is high" and that "an unacceptable risk may exist from consumption of raw and processed agricultural commodities treated with daminozide." These conclusions were repeated in the notice of special review (PD-1). In particular, the agency stated in both documents that it was "particularly concerned" about the exposure of young children to daminozide and UDMH, because young children "consume large quantities of apple products" containing increased concentrations of UDMH. Registration Standard, p. 22; 49 Fed. Reg. 29136, 29138-39 (July 18, 1984).

31. In the draft PD 2/3/4, EPA estimated that infants are exposed to daminozide and UDMH at levels 10 to 15 times higher than adults. Children under six are exposed at levels four times higher than adults. In light of these findings, together with the fact that daminozide and UDMH were found to be probable human carcinogens, the agency stated that it had "determined that the dietary risks outweigh the benefits associated with [daminozide's food] uses." Therefore, the agency proposed "to cancel all food uses of daminozide." PD 2/3/4, Executive Summary, p. 2.

32. State officials have also found that daminozide exposure levels are unacceptable, particularly to young children. Stephen Havas, M.D., Deputy Commissioner of Public Health, Commonwealth of Massachusetts, concluded that "[a]ll testimony [presented to the Commission] indicated that children have higher levels of exposure to daminozide and UDMH due to their increased consumption of apple products." (Exhibit 7, p. 8). The Director of the Massachusetts Department of Public Health, Division of Food and Drugs, concluded that EPA has failed to "offer adequate health protection to the general public and in particular, to infants and young children who consume a disproportionate amount of apple products." (Exhibit 4). The Maine Department of Human Services, Bureau of Health found in its risk assessment that "infants and children, because they ingest proportionately larger amounts of processed apple products, and because they are at a biologically sensitive stage of development, are at greatest risk." (Exhibit 5).

33. The failure of Uniroyal or EPA to demonstrate the safety of the daminozide tolerances is especially troubling because infants and children are likely to be at greater risk from exposure to daminozide and UDMH. This increased risk is a function both of greater exposure to the chemicals and increased susceptibility to carcinogenic agents. Children eat more food, per unit of body weight than adults. In part for this reason, according to one independent scientist, infants and children consume between 6 and 19 times more apple products per unit of body weight than adults. Ian Nisbet, Ph.D., Statement Presented at Public Hearings of the Massachusetts Department of Public Health on Proposed Regulations to Enact Action Levels for Daminozide in Food, p. 4 (March 14, 1986) (Exhibit 9). Children also consume disproportionately more apple sauce and apple juice — the products that are reported to have the highest levels of UDMH. Therefore, doses of UDMH ingested by children may be at least

10 times higher than those for adults. *Id.* In the draft PD 2/3/4, EPA estimated that infants and children under the age of six may be exposed to five to 14 times more daminozide than adults. PD 2/3/4, p. II-51.

34. In recognition of the special susceptibility of infants and young children, the Massachusetts Department of Public Health computed the added risks to young children from daminozide exposure. Assuming that apple product consumption by children is approximately 12 times greater than adults, the Department calculated that daminozide exposure in the first three years of life would produce 32 percent of the excess cancer risk that would be incurred by lifetime exposure. The Department scientists concluded that the "calculation underscores the importance of eliminating exposure to children, and of rapid elimination of such exposure" and more generally urged "caution in setting tolerances for food products consume[d] by young children." Massachusetts Department of Public Health, *Daminozide Carcinogenicity and Risk Assessment (Executive Summary)* (May 13, 1986) (Exhibit 6).

35. Another reason children are at greater risk than adults results from the multistage nature of cancer development, specifically the sequential development of cancer from initiated cells. Cells exposed to cancer initiators early in life have more chance to progress to fully-developed cancers simply because they have more time during which late-stage transitions can occur. Children are also at greater risk because their cells may be inherently more sensitive to cancer initiators, and because their organs are developing and new cells are being generated at a high rate. *See* Memorandum to Commissioner Bailus Walker from Deputy Commissioner Stephen Havas, M.D., pp. 8-9 (Exhibit 7); Statement of Dr. Ian Nisbet (Exhibit 9).

36. In sum, existing exposure levels and dietary risks from daminozide and UDMH are high, particularly to infants and young children. In light of these findings, the current tolerance levels must be reevaluated and set at zero.

DAMINOZIDE AND UDMH RESIDUES IN FOOD PRODUCTS ARE CAUSING CONSUMER CONCERN AND FOOD PROCESSORS ARE REFUSING TO ACCEPT DAMINOZIDE-TREATED COMMODITIES.

37. The recent decision of several major food processors not to accept commodities treated with daminozide provides further evidence of the lack of assurance of the safety of daminozide residues. *See* "Polishing the Apple's Image," *New York Times* (May 25, 1986) (Exhibit 10). In December 1984, the National Grape Co-operative, Producers of Welch's Quality Grapes, notified its members that grapes treated with daminozide would not be accepted for processing. Further, the Co-operative stated that it intended to urge "the Concord Grape Association to adopt the same posture. The goal will be to effect a total industry ban on Alar until such time as it may be certified as safe for use in the vineyard." More recently, Tree Top Inc., the world's largest apple juice processor, decided to stop using apple products treated with daminozide. Producers of Mott's apple products, Veryfine and Red Check apple juice have informed growers and suppliers that daminozide-treated apples will not be purchased. Finally, Heinz, Beech Nut, and Gerber are refusing to accept daminozide-treated apples for processing into baby food. These actions demonstrate broad-based food industry concern over daminozide's safety and provide further support for establishment of zero tolerances for the pesticide.

COUNT 1 — EPA Must Establish Zero Tolerances for Daminozide Under Section 408 of the Federal Food, Drug and Cosmetic Act.

38. Section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. § 346a(b), requires EPA to establish tolerances "to the extent necessary to protect the public health." The law is well-settled that the registrant — in this case Uniroyal — has a continuing burden of demonstrating that existing tolerances are "safe" for the consuming public. Where the scientific data fail to demonstrate the safety of pesticide residues, EPA is authorized to establish a zero tolerance. *Id.*

39. Congress intended to place the burden of demonstrating the safety of tolerance levels on the registrant. As stated in the FFDCA House and Senate Reports, "scientific data must be presented to show that the pesticide chemical is safe from the standpoint of the food consumer" before a tolerance above zero can be established. Furthermore, "[t]he burden is on the person proposing the tolerance or exemption to establish the safety of such pesticide-residue." H.R. Rep. No. 1385, 83rd Cong., 2d Sess., 5 (1954); S. Rep. No. 1635, 83rd Cong., 2d Sess., 4, *reprinted in* 1954 U.S. Code Cong. & Ad. News 2629.

40. Congress imposed upon the registrant a continuing burden of demonstrating the safety of existing tolerance levels. As stated by the U.S. Court of Appeals: "Once new evidence bearing on the safety of pesticide residues has been adduced or cited sufficient to justify reopening the issue of the validity of existing tolerances,... the burden of establishing the safety of any tolerance remains on those who seek to permit a residue." *Environmental Defense Fund, Inc.* v. *HEW*, 428 F.2d 1083, 1092 n.27 (D.C. Cir. 1970).

41. In establishing or revising a tolerance level, the FFDCA requires EPA to establish a level that will protect the public health. Other factors, such as "the production of an adequate, wholesome, and economical food supply," 21 U.S.C. § 346a(b), may only come into play in determining which "safe" level to adopt. In other words, EPA may not compromise public health in setting tolerance levels, but rather must ensure that tolerances are safe from the consumer's perspective.

42. Under the FFDCA, a zero tolerance is required under at least two circumstances. First, where the evidence demonstrates that a pesticide is carcinogenic, there may be no way to establish a "safe" level. *EDF v. HEW*, 428 F.2d at 1092; 40 C.F.R. Sec. 180.5(b) (1985) (authorizing a zero tolerance when "the chemical is carcinogenic to...test animals"). At a minimum, the EPA Administrator "would, of course, be required to explain the basis on which he determined such tolerances to be 'safe.'" *EDF v. HEW*, 428 F.2d at 1092. Second, a zero tolerance is appropriate when available data are inadequate to establish a higher level. 21 U.S.C. Sec. 346a(b); 40 C.F.R. Sec. 180.5(a) (authorizing a zero tolerance when "a safe level of the pesticide ... has not been readily determined"). Both of these principles apply here.

43. As set forth above, studies prepared since establishment of the original tolerances demonstrate that daminozide and UDMH are animal carcinogens and probable human carcinogens. These studies are sufficient to justify reopening the issue of the validity of existing tolerances. Given the significant risks and exposure levels, EPA should immediately propose establishment of zero tolerances for daminozide. A zero tolerance is appropriate for two reasons: first, available evidence demonstrates that daminozide is carcinogenic; and second, the evidence is not adequate to justify the safety of a level higher than zero. A zero tolerance should be established until and unless the registrant can satisfy

the burden of demonstrating the safety of a higher level.

COUNT 2 — EPA Must Revoke the Existing Tolerances for Daminozide in Processed Foods Under Section 409 of the FFDCA.

44. Section 409 of the FFDCA, 21 U.S.C. § 348, authorizes EPA to establish separate tolerances for pesticides found in processed foods at levels higher than allowed by tolerances established for raw agricultural commodities, 21 U.S.C. § 342(a)(2)(C); 21 C.F.R. § 170.19 (1985). but only if such tolerances can be established at a level that "will be safe." 21 U.S.C. § 348(c)(3)(A). As interpreted by the agency, "'safe' or 'safety' means that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use." 21 C.F.R. § 170.3(i) (1985). Under any circumstances, no food additive tolerance may be established for any substance that has been "found ... to induce cancer in man or animal." 21 U.S.C. § 348(c)(3)(A) (the "Delaney Clause").

45. Daminozide has apparently been found in processed foods, including tomatoes and dried prunes, at levels far above the tolerances in raw commodities. *See* 21 C.F.R. § 193.410 (1985) (setting forth tolerances in processed foods). In light of the new information demonstrating that daminozide and UDMH are animal carcinogens and probable human carcinogens, the Delaney Clause prohibits the establishment of a tolerance in processed foods. Moreover, the Delaney Clause prohibits residues of UDMH, a known carcinogen, in food. In any case, existing tolerances for daminozide are clearly not safe. Accordingly, EPA should revoke the tolerances as soon as possible.

PRAYER FOR RELIEF

46. Studies prepared after establishment of the daminozide tolerances establish that both daminozide and UDMH are animal carcinogens and probable human carcinogens. Under the circumstances, Section 408 of the FFDCA requires the agency to reopen the issue of the validity of existing tolerances and to propose amended tolerances at zero. The burden of proof must be placed on the registrant to demonstrate, from the consumer's perspective, the safety of any higher tolerance. Because this burden has not and cannot be met, final regulations establishing zero tolerances for daminozide on raw commodities should be issued as soon as possible.

47. In light of the studies demonstrating that daminozide and UDMH cause cancer in laboratory animals, Section 409 of the FFDCA requires that the tolerances for daminozide in processed foods be revoked. In any case, the existing tolerances are clearly not "safe" as defined in the agency's regulations. Accordingly, the tolerances should be revoked.

48. EPA has been aware of daminozide's carcinogenicity since at least 1977. Despite this knowledge, EPA has failed to take any action to eliminate existing tolerances. Such action is long overdue. Given the significant risks and exposure to daminozide, particularly for infants and young children, EPA should take immediate action to establish zero tolerances. Petitioners hereby request that the agency respond to this petition by issuing a proposed rule within 30 days, and a final rule within 90 days after the acceptance of this petition (the applicable deadlines for agency actions pursuant to a registrant's petition). *See* 40 C.F.R. § 180.7 (1985); 21 C.F.R. §§ 171.1, 171.100 (1985). If the agency does not respond within this deadline, we will consider this petition to have been denied.

REQUEST FOR WAIVER OF FEES

49. Petitioners are non-profit organizations, states, and individuals lacking an economic interest in the establishment and revision of tolerances. A requirement that we pay the fees that ordinarily must accompany tolerance requests would constitute an unreasonable financial burden and would effectively preclude us from filing this petition. Given the serious health and safety issues raised by the petition, there is a strong public interest in having the issues entertained and resolved. Accordingly, we request a waiver of the customary fees, as authorized by the FFDCA and implementing regulations. 21 U.S.C. Sec. 346a(o); 40 C.F.R. Sec. 180.33(1) (1985).

Date: July 1, 1986

Respectfully submitted:

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20400

Jan. 6, 1987

Office of Pesticide
and Toxic Substances

Bill Schultz
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In re: Petition for Establishment of
Zero Tolerances for Daminozide

Dear Petitioners:

This letter is in response to your petition requesting the Environmental Protection Agency to amend existing food tolerances for the pesticide daminozide and reestablish the tolerances at zero. This petition was filed on behalf of the Natural Resources Defense Council, Public Citizen, the State of New York, the Maine Department of Human Services, and several pediatricians and young children (hereinafter referred to as "Petitioners"). Your petition argues that daminozide and its contaminant/breakdown product, UDMH, are potent carcinogens and that existing food tolerances are inadequate to protect the public health. Of particular concern to Petitioners is the potential risk to infants and young children who consume significant amounts of apple products, which may contain residues of daminozide and UDMH.

The Agency has carefully evaluated the information submitted by the Petitioners, in conjunction with all other data and information on daminozide available to the Agency. Based on this evaluation, the Agency has determined that the available data are

not adequate to enable the Agency to determine whether the long-term presence of daminozide residues in food poses a health hazard to the U.S. consumer. Accordingly, the Agency has required the registrant of daminozide to conduct four additional oncogenicity studies, as well as mutagenicity studies, metabolism studies, and extensive residue monitoring studies. Most of these data should be available to the Agency within two years. In the interim, the Agency is taking a number of steps to limit the exposure of the American public to daminozide. First, the Agency will reduce the tolerance of daminozide on apples to 20 ppm, the lowest level necessary to achieve the benefits of use of daminozide on that commodity. The Agency will initiate tolerance revocation actions for daminozide on plums, melons, brussels sprouts, and peppers, use patterns for which the registrations of daminozide have been cancelled. For the remaining tolerances on other commodities, as additional residue data become available, the Agency will determine whether any tolerance reductions can be achieved for the interim period without eliminating the benefits of use of the chemical. With regard to tomatoes, the Agency is reviewing the data base and will propose a reduction in the tolerance for tomatoes and the food and feed regulations for processed tomato products and dried tomato pomace. Finally, the Agency has determined that the existing food additive regulations are no longer necessary for daminozide on prunes, and will take action to revoke this regulation. A Federal Register notice proposing this revocation action is anticipated to be published by March 4, 1987. A discussion of the reasons for these Agency actions and the Agency's analysis of the petition are presented below.

I. REGULATORY HISTORY OF DAMINOZIDE

Daminozide (Alar) is a plant growth regulator registered for

use to control the vegetative and reproductive growth of orchard crops such as apples, cherries, grapes, nectarines, peaches, and pears. The major use of daminozide is on apples. It is also used to produce shorter and more erect peanut vines, and enhance green coloration and yield, retard stem growth in tomatoes and to control the stem length and shape of ornamental plants. Tolerances have been established to allow the presence of daminozide residues on the commodities for the above registered food uses; a number of tolerances remain for crops on which daminozide is no longer registered for use.

Between 1983 and 1978, the Agency received four cancer studies indicating positive carcinogenic responses to daminozide and its breakdown product and contaminant, UDMH. Two of these studies tested daminozide, and two were conducted with UDMH. One daminozide study, conducted by the National Cancer Institute in 1978, indicated that the feeding of daminozide caused uterine cancer in female rats, and unclear results with respect to hepatocellular carcinomas in male mice. The second daminozide study correlated the administration of daminozide in drinking water with statistically significant increases in blood vessel and lung tumors in male mice, and kidney and liver tumors in male mice (Toth, 1977). A 1973 study by Toth showed that the administration of UDMH containing drinking water to male and female mice resulted in statistically significant increases in blood vessel and lung tumors in these test animals. Finally, a 1977 Toth study with Syrian golden hamsters indicated that the administration of UDMH in drinking water resulted in significant increases in blood vessel and intestinal tumors.

Based on these studies, the Agency notified the manufacturer of daminozide in 1980 that a Special Review of daminozide was under consideration. Rather than initiate a Special Review at that

time, the Agency decided to review the entire daminozide data base through the Registration Standards process. During the course of this review, the Agency determined that additional data were necessary to complete its evaluation of the potential hazard posed by daminozide and UDMH. The Agency was particularly concerned about UDMH formation because of its alkylating properties and evidence of its genotoxicity and carcinogenicity. However, the Agency was unable to determine the dietary risk posed by daminozide because complete information was not available on 1) the rate of conversion of daminozide to UDMH in the human stomach; 2) the presence of UDMH and daminozide in raw and processed foods; and 3) the level of UDMH residues in meat, milk, and eggs as a result of feed containing daminozide or UDMH. A data call-in notice was issued on August 25, 1983, requiring the registrants to generate, among other things, 1) studies showing the mechanism and rate of UDMH conversion in conditions simulating the human stomach and in an animal model; 2) a residue study on apples to determine the amount of daminozide and UDMH present; 3) a plant metabolism study to determine the fate of daminozide and UDMH in treated plants; 4) residue field trials to determine the amount of daminozide and UDMH present in all commodities for which a tolerance was established; 5) a study examining the conversion of daminozide to UDMH under conditions of food preparation and food processing; and 6) an animal metabolism study to determine whether UDMH or other metabolites are found in meat, milk, poultry, or eggs.

The manufacturer of daminozide, Uniroyal Chemical Co. voluntarily cancelled the use of daminozide on several crops, including plums/prunes, brussels sprouts, peppers, cantaloupes, and the late treatment of tomatoes rather than generating the necessary residue data on these commodities required by the data call-in notice. Aceto Chemical Company, which also has a

registration for daminozide, did not comply with the data call-in notice, and its registration was suspended.

In July, 1984, the Agency issued a Registration Standard for daminozide. With regard to oncogenicity, the Agency concluded that:

- Daminozide had demonstrated oncogenic effects in laboratory animals and is contaminated with hydrolyzes to UDMH, a known animal oncogen.

- Significant exposure to daminozide and UDMH can occur via consumption of raw and processed agricultural commodities treated with daminozide.

- There was not enough residue data available to complete a reassessment of all daminozide tolerances.

- Without daminozide, short term revenue losses were projected to range up to $30 million annually for apples and from $4.3 to $1 million annually for peanuts, the two largest daminozide use crops.

- A Special Review would be initiated and no additional uses or products would be registered until the Special Review was completed.

The Registration Standard also required additional chronic toxicity testing and residue data (beyond the requirements of the 1983 data call-in notice).

On July 18, 1984, the Agency published a notice of initiation of the Special Review of daminozide on the basis of positive oncogenicity studies in rats and mice for daminozide and in mice

and hamsters for UDMH. During the course of the Special Review, the Agency audited the Toth mouse study on daminozide in response to claims by the registrant that the carcinogenic potential of daminozide had been overstated and the test procedures and results of the study had not been validated. Although deficiencies in the conduct of the daminozide study were noted, the Agency auditors concluded sufficient information was available to very that daminozide induced a highly significant increase in the incidence if blood-vascular tumors in the test animal.

During 1985, the Agency received a chronic inhalation study with UDMH on dogs, hamsters, rats, and mice, conducted at the Air Force Aerospace Medical Research Laboratory in Ohio. No increases in tumors over controls were demonstrated in either dogs or hamsters. However, the study reported an increase un hemangiosarcomas and Kupfer cell sarcomas in female mice. Purified UDMH also produced adenomas/carcinomas in the lung and liver as well as nasal tumors in the female mice. Male rats reportedly exhibited bronchiolar adenomas and pancreatic islet adenomas and carcinomas.

The Agency's draft Position Document 2/3/4 (PD 2/3/4), released on September 12, 1985, concluded that daminozide and UDMH were B2 carcinogens under the Agency's cancer assessment guidelines, and estimated the dietary cancer risk from exposure to daminozide and UDMH to range from 10^{-4} to 10^{-3}/ 10^{-2}. The Agency also determined that children and infants are exposed to 2 to 14 times as much daminozide or UDMH per kilogram of body weight as adults because of their high consumption of apples and apple based products and the fact that children consume more food per body weight than adults.

The benefits of daminozide were estimated in terms of

economic impact which would result from cancellation. Most affected would be the apple industry, with an estimated $31 million annual loss.

In the draft document, the Agency proposed the cancellation of all food uses of daminozide based on a determination that there were no measures short of cancellation which would reduce dietary risks sufficiently such that these risks would be out-weighed by the benefits. This proposed decision was submitted to the Agency's Scientific Advisory Panel (SAP) for review. The SAP noted that the Toth studies did give rise to concern over the potential oncogenicity of daminozide, but concluded that the available data were inadequate to perform a qualitative risk assessment for daminozide. Reservations were expressed by the Panel about the quantitive soundness of the Agency's dietary risk assessment for both daminozide and UDMH, with particular concern that the residue levels used by the Agency were not reflective of actual residue values. In the Panel's view, appropriate quantitative risk assessments could not be carried out until adequate data were available.

After considering the opinion of the SAP, the Agency imposed extensive data requirements on Uniroyal on February 10, 1986, and adopted the SAP's recommendation to delay a final decision on the continued food uses of daminozide until sufficient data were available. Key among the required studies are the rate and the mouse UDMH chronic feeding/oncogenicity studies. Interim sacrifices are required at 8 months and 12 months for the mice (reports due Sept. 1987 and March 1988, respectively) and at 12 months for the rats (report due March 1988). The final report is due in July, 1989. If results from interim sacrifices demonstrate that regulatory action is warranted, the Agency will take an appropriate action prior to the conclusion of the study. Uniroyal has also initiated a chronic feeding/oncogenicity study

with daminozide in rats and mice; the final report on this study is expected by August, 1988.

In the interim, the Agency has taken measures to reduce exposure to daminozide. In particular, the Agency has approved a label amendment which reduces the application rate for apples. Moreover, the registrant has committed to include a use advisory on every bag of Alar 85 recommending that daminozide treated apples not be sold for processing into sauce, and has limited the production of daminozide products labeled for use on grapes. Based on residue measurements at the reduced application rate, the Agency has also issued a proposal to reduce the daminozide tolerance on apples from 30 ppm to 20 ppm. 51 Fed. Reg. 12889 (April 16, 1986).

II. LEGAL BACKGROUND

The Federal Food, Drug and Cosmetic Act (FFDCA) authorizes the establishment of tolerances and exemptions from tolerances for residues of pesticide chemicals in or on raw agricultural commodities pursuant to § 408, and the promulgation of food additive regulations for pesticide residues in processed food under § 409 of that Act.* Without such tolerances, exemptions from tolerances, or food additive regulations (sometimes also referred to as "tolerances"), a food is "adulterated" under § 402 of the FFDCA, and hence may not legally move in interstate commerce. Pursuant to § 402(a)(2)(C) of the FFDCA, a food additive regulation must be established for processed food if the

*Under the Reorganization Plan that established EPA in 1970, the authority to set tolerances for pesticide chemicals in raw agricultural commodities and processed food under §§ 408 and 409 of the FFDCA was transferred from the FDA to EPA. The FDA retains the authority to enforce the tolerance and food additive provisions under this Plan.

pesticide residue in the processed food is greater than the tolerance prescribed for the raw agricultural commodity. Where, however, the pesticide residues in the processed food resulting from the "carryover" from treatment of the raw agricultural commodity do not exceed the tolerance level established for the raw agricultural commodity, a separate food additive regulation is not necessary. § 402(a)(2)(C).

To establish a tolerance or an exemption under § 408, the Agency must make the finding that the promulgation of the rule would "protect the public health." § 408(b). In reaching this determination, the Agency is directed to consider, among other relevant factors, 1) the necessity for the production of an adequate, wholesome, and economical food supply; 2) other ways in which the consumer may be affected by the pesticide; and 3) the usefulness of the pesticide for which a tolerance is sought. Thus, in essence, § 408 of the FFDCA gives the Agency the authority to balance risks against benefits in determining appropriate tolerance levels. The Agency is permitted to set a tolerance at zero "if the scientific data before the Administrator does not justify the establishment of a greater tolerance." § 408(b).

The breadth of Congress' mandate to the Agency is supported by the legislative history, which addressed many times over the latitude granted the AGency in balancing risks and benefits in promulgating a tolerance rule. For example, in discussing section 408(b), the Senate noted:

> This subsection gives to the Secretary of Health, Education, and Welfare the authority to establish tolerances. The subsection also sets forth the principal factors which should guide the administrative judgment in taking such action. The factors are designed to assure a proper balance between the need for protecting the consumer and the need for

assuring an adequate, wholesome, and economical food supply.

S. Rep. No. 1635, 83d Cong., 2d Sess. at 7 (1954). *See* also H.R. Rep. No. 1835, 83d Cong., 2d Sess. at 2, 3, 4 (1954); S. Rep. No. 1635, 83d Cong., 2d Sess. at 3, 4 (¶1) (1954).

Moreover, the U.S. Court of Appeals for the D.C. Circuit has addressed the standard found in § 408 and concluded that the Agency can weigh the risks and benefits for carcinogenic, as well as non-carcinogenic, pesticides. *Environmental Defense Fund v. United States Dept. of Health, Education and Welfare*, 428 F.2d 1083, 1086-87, 1091 (D.C. Cir. 1970). In that case, the Court clearly indicated that the restrictions of the Delaney clause of § 409 of the FFDCA do not apply to § 408. *Id.* at 1091.

Moreover, the statute and its legislative history are clear that § 408 merely authorizes, and does not explicitly require a "zero tolerance" in the absence of adequate data to justify a higher level.* Amendments were placed before Congress which would have made such a zero tolerance mandatory, at least with regard to pesticides which presented a risk of chronic toxicity. *Residues of Pesticide Chemicals, Hearings before Subcommittee on Health of the Senate Committee on Labor and Public Welfare* at 64 (June 23, 1954); *See also, id.* 53-76. Yet Congress refused to require such action, and instead enacted § 408(b), which clearly only provides that the Agency "may establish" a zero tolerance, not that it is required to take such action.

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*Similarly, EPA's regulations at 40 C.F.R. § 180.5 interpret the regulatory scheme to give discretion to the Agency in determining when to set zero tolerances. The regulations do not require the establishment of a zero tolerance in any particular situation, but merely enumerate situations where the Agency *may* find it appropriate to establish such tolerances.

The establishment of a food additive regulation under § 409 requires a finding that the pesticide "may be safely used." FFDCA § 409(a). Relevant factors in this safety determination include 1) the probably consumption of the pesticide or metabolites; 2) the cumulative effect of the pesticide in the diet of man or animals, taking into account any related substances in the diet; and appropriate safety factors to relate the animal data to the human risk evaluation. Section 409 contains the Delaney Clause, which specifically provides that no additive is deemed safe if it induces cancer when ingested by man or animals, except for an ingredient of animal feed, if such ingredient will not adversely affect the animal and no residues of the substance will be found by an Agency approved method in any edible food yielded or derived from the treated animal ("DES Proviso").

Under §§ 408 and 409 of the FFDCA, the proponent of a tolerance or a food additive regulation has the burden of providing data establishing the safety of the pesticide for which a tolerance (or food additive regulation) is sought. § 408(d)(1); § 409 (b)(2). As noted by both the House and Senate reports:

> Before any pesticide-chemical residue may remain in or on a raw agricultural commodity, scientific data must be presented to show that the pesticide chemical is safe from the standpoint of the consumer. The burden is on the person proposing the tolerance or exemption to establish the safety of such pesticide-chemical residue.

H.R. Rep. No. 1385, 83d Cong., 2d Sess. at 5 (1954); S. Rep. No. 1635, 83d Cong., 2d Sess. at 4 (1954). Once a tolerance (or food additive regulation) has been established, the burden of justifying the continued safety of the pesticide residues authorized by the rule remains with the proponent of such rule. *EDF* v. *HEW*, 428 F.2d at 1092, n. 27.

Sections 408(m) and 409(h) of the FFDCA give the Agency authority to revoke or amend established tolerances at its discretion. These statutory provisions do not provide explicit guidance to the Agency regarding the timing of such revocation actions. Thus, for example, where new evidence raises questions about the appropriateness of an established tolerance rule, there is no directive in the FFDCA either to initiate a revocation action promptly or allow a reasonable time for data generation. However, a consideration of the regulatory approach of the closely interrelated provisions of FIFRA indicates that allowing a reasonable time for data generation is proper in appropriate situations.

Specifically, FIFRA provides a detailed regulatory scheme for addressing the situation where additional data is required to establish the safety of a registered pesticide. FIFRA gives the Agency the authority to require additional data to support the continued registration of a pesticide under § 3(c)(2)(B), and explicitly provides that the Agency must "permit sufficient time for applicants to obtain such additional information." § 3(c)(2)(A). Cancellation of a registration is not appropriate under this regulatory scheme unless the available evidence indicates that the risks of use of a pesticide outweigh the benefits. § 6(b). Since the Agency is charged with the task of regulating pesticides under both the authority of FIFRA and the FFDCA, the objectives of both of these statutes must be reconciled to achieve a common sense result. To be consistent with the directives of FIFRA in the situation where additional data have been requested pursuant to § 3(c)(2)(B), the Agency must allow a reasonable amount of time for the proponent of the tolerance rule to meet the burden of establishing the continued safety of the pesticide residues. Otherwise, the Agency would be in the position of having to revoke a tolerance rule, while leaving the corresponding food crop registration intact during the time

necessary for data generation under § 3(c)(2)(B). The revocation of the tolerance would be tantamount to the cancellation of the registration in contravention of the directive of § 3(c)(2)(A). This approach would create havoc for food growers, processors, and suppliers, and deprive the economy of the value of many useful pesticides. Such a result is clearly not consistent with the Congressional directive to regulate the use of pesticides to allow the beneficial use of these chemicals as long as there are no unreasonable adverse effects on the environment and the public health is protected. Of course, in those situations where the available data indicate that the risks of use exceed the benefits, the Agency would take action under section 6 of FIFRA to issue a cancellation notice, and would initiate rulemaking to revoke the corresponding tolerances and food additive regulations.

III. RISK CONCERNS RELATED TO DAMINOZIDE

The primary concern regarding the presence of residues of daminozide and UDMH in food relates to the possibility that these chemicals may pose a risk of cancer to consumers. This concern was the primary risk basis for the proposed action in 1985 to cancel the registrations of daminozide for use on food. Petitioners have identified five studies which they argue demonstrate that daminozide and its metabolite, UDMH, pose a risk of cancer: *Haun 1984, NCI 1978, Toth 1977a, Toth 1977b,* and *Toth 1973*. Each of these studies, however, has been examined by the Agency and the FIFRA Scientific Advisory Panel (SAP) and has been found not to provide an adequate basis for regulatory action at this time.

The Haun Study

In the *Haun 1984* study, animals were exposed to a test substance reported to be UDMH as gas, and an increase in tumor incidence was observed. A recent Agency audit, however, found the *Haun 1984* study inappropriate for regulatory reliance under FIFRA. Report of a Data Audit Conducted at the Air Force Aerospace Medical Research Laboratory, Wright-Patterson Air Force Base...on January 28-30, 1986. Specifically, the chemistry reviewer found that, contrary to the statements in the published reports, 1) much of the test substance was not redistilled; 2) no tests were performed to determine the chemical purity of the test substance; 3) the boiling point of the test substance was 30-40 degrees C different from the literature value for the boiling point of UDMH; and 4) the test used to determine whether the nitrosamine contaminant of UDMH had been removed was unreliable. *Id.* Based on these findings, the reviewer determined "the study should not be accepted as valid for regulatory purposes." *Id.* In addition, the audit team found discrepancies in the reporting of data. *Id.*

The NCI Study

The *NCI 1978* bioassay was conducted in both mice and rats with exposure of the animals to daminozide in dry food. This study was apparently well-conducted, but used only 20 control animals per sex per species, resulting in "extremely low statistical power." Agency Peer Review of Oncogenicity of Daminozide, April 5, 1985, p. 8. No indication of carcinogenicity was found in the male rats or female mice. Draft PD2/3/4 at II-20. In the male mice there may have been an association of daminozide treatment with development of hepatocellular carcinomas, but the investigators, after comparing the results to historical control

values, found that the relationship was "not clear." *Id. NCI 1978* at 36. Finally, the NCI study indicated that daminozide may induce adenocarcinomas of the endometrium of the uterus and leiomyosarcomas of the uterus in female rats; there was no significant relationship when compared to concurrent controls, but there was when compared to historical controls. *NCI 1978* at 35-36. EPA found these results in the female rats "to be only marginally statistically significant." Peer Review of Oncogenicity of Daminozide at p. 8.

In a subsequent review of the NCI Bioassay by a Department of Health, Education and Welfare peer review, two reviewers expressed divergent views of the meaning of the study. The primary reviewer stated that the NCI study showed "Daminozide was, at most, a borderline carcinogen in female rats." *NCI 1978* at 113. The secondary reviewer, however, believed that the NCI bioassay showed daminozide to be carcinogenic in female rats and male mice. *Id.*

The Toth Studies

The three Toth studies (*Toth 1977a, Toth 1977b*, and *Toth 1973*) displayed a statistically significant relationship between administration of daminozide or UDMH and the development of tumors, but also had numerous flaws which undercut their reliability for regulatory decision-making. These studies involved exposure to UDMH in drinking water in mice (*Toth 1973* and hamsters (*Toth 1977b*) and exposure to daminozide in drinking water in mice (*Toth 1977a*). In *Toth 1977a*, after exposure to daminozide, male mice showed statistically significant increases of tumors in the lung, kidney, and blood vessels, and female mice displayed statistically significant increases in tumors in the lung and blood vessels. Draft PD-2/3/4 at II-21. In

Toth 1977b, male and female hamsters exposed to daminozide showed some increases in various tumors, including tumors of the blood vessels and the cecum. *Id.* at II-26. In *Toth 1973*, statistically significant increases in blood vessel, lung, and kidney tumors were observed in mice exposed to UDMH in drinking water.

A number of flaws limit the reliance that can be placed on the results of these studies. Specifically, 1) the studies did not use the concurrent control groups in the published report, but relied only on historical controls; 2) only a single dose level was used in each study; 3) control groups were housed in the same animal room as test groups and more than one chemical was tested in the room simultaneously; 4) there was a possibility of cross-contamination in dose preparation rooms; 5) the quality assurance procedures were limited; 6) the maximum tolerated dose of the test substance was apparently exceeded; and 7) there were differences between the antibiotic treatment of controls and test animals. Memorandum from Esther Saito to Walt Waldrop, Special Review Branch, Registration Division, September 23, 1986; EPA Audit Report. Finally, the number of test animals in Toth 1977b was extremely limited (no more than 10 hamsters in each test group), raising questions about the significance of the results. Draft PD 2/3/4 at III-26.

An earlier study, *Oser 1966*, revealed no indication of carcinogenicity after administration of daminozide in feed. EPA is unaware of any other studies which might be adequate for regulatory purposes regarding the carcinogenicity of either daminozide or UDMH.

IV. BENEFITS OF DAMINOZIDE

The substantial benefits of the registered uses of daminozide were discussed at length in the Draft PD 2/3/4 at III- 1 to III-23. The major crop treated with daminozide is apples. Daminozide provides a wide range of benefits for apples, including increased storage life, fruit drop prevention, improved color, reduced watercore, maintenance of firmness, and reduced storage scald. The cancellation of daminozide would result in estimated lost profits to the apple growers of $31 million per annum. Current total profits to the apple growers are in the range of $200-300 million dollars annually. There would also be a significant impact on consumers because fewer fresh apples would be available and the price of retail fresh apples would rise, on the average, by $1-1.90 per bushel. Losses attributable to the cancellation of registrations for use of daminozide on peanuts, cherries, nectarines, peaches, pears, grapes, and tomatoes would be generally lower than for applies. For most of these uses, however, there are no alternative pesticides to daminozide as growth regulators for these crops.

V. REGULATORY ACTION

Existing tolerances in 40 C.F.R. § 180.246 allow the presence of daminozide residues* in or on apples, nectarines, peaches, peanuts, and sweet cherries at 30 ppm. Tolerances also have been established for sour cherries (55 ppm); plums (fresh prunes)(50 ppm); tomatoes (40 ppm); brussels sprouts, peanut hay and pears

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*The current tolerances and food additive regulations are set in terms of daminozide residues. However, under the Agency's regulations, UDMH falls under the definition of "residue", which includes a "degradation product" which can be found "following the use of the pesticide." 40 C.F.R. § 162.3 (kk). The analytical method for determining the levels of daminozide residues also measures the amount of UDMH which is present, and therefore the tolerance level actually reflects both daminozide and UDMH residues.

(20 ppm); grapes and peanut hulls (10 ppm); melons (3 ppm); poultry kidney (2 ppm); peppers (1 ppm); meat, fat, and meat byproducts of cattle, goats, hogs, horses, poultry (except poultry kidney) and sheep (0.2 ppm); eggs (0.2 ppm), and milk (.02 ppm)(negligible residue). Food additive regulations currently exist in 21 C.F.R. § 193.410 for only two food commodities: dried prunes (135 ppm) and concentrated tomato products (320 ppm). Feed additive regulations currently exist in 21 C.F.R. § 561.360 for two feed commodities: dried potato pomace (600 ppm) and peanut meal (90 ppm).

The Agency intends to initiate tolerance revocation actions for daminozide on plums, melons, brussels sprouts and peppers. Because the registrations for daminozide on these crops have been cancelled, there presumably are no benefits of continued use of daminozide for production of an adequate, wholesome, and economical food supply with regard to these crops. Accordingly, the revocation of these tolerances is appropriate. The Agency will also take action to reduce the current tolerance level on tomatoes. Because of changes in the use pattern, residues in this raw agricultural commodity are considerably lower than the current established tolerance.

The Agency is also planning to take action to revoke the food additive regulation for daminozide on plums and to reduce the food/feed additive regulations on processed tomato products and dried tomato pomace. Since the registration for the use on plums (to make prunes) has been cancelled, there is no longer any need for the food additive regulation on dried prunes. With regard to the regulations on processed tomato products and dried tomato pomace, recent residue data indicate that residues are well below the current limitation because of changes in the use pattern of daminozide. Therefore, the Agency will take action to reduce the food/feed additive regulations for daminozide in processed

tomato products and dried tomato pomace.

The Agency has already issued a proposed rule to amend the tolerance for daminozide on apples from 30 ppm to 20 ppm. 51 Fed. Reg. 12889 (April 16, 1986). This interim tolerance rule would expire on July 31, 1987. By that date, the Agency will have received the results of the residue field trials, due in May 1987, and will be in a position to reassess the tolerance for daminozide on apples. During the interim period the 20 ppm tolerance will assure reduced exposure to consumers from daminozide residues with a corresponding reduction in risk. Any risk that remains is expected to be minimal, particularly in light of the very short period involved.

The Agency has also concluded that the public health will be protected during the time period necessary to generate the additional data which will address the Agency's long-term concerns about daminozide residues in food. As discussed above in this response, Congress has provided the Agency with the latitude to allow time for data generation in appropriate situations. On the basis of available data, the Agency does not believe that a zero tolerance is warranted because of the low potential risk during the time period necessary to generate the required data.

Data have also been required in support of the other remaining food uses of daminozide. As these data become available, the Agency will take appropriate action to adjust the tolerances to reflect levels that are no higher than necessary to achieve the benefits of use of the chemical. The Agency does not believe that the presence of daminozide residues in or on the raw agricultural commodities enumerated above poses a risk of concern to the consumer during the time necessary for data generation.

In conclusion, the Agency believes that it is taking responsible action to reduce the levels of daminozide in food during the time necessary for the registrant to submit data to resolve the Agency's concerns about daminozide. Since definitive data on risk and exposure are not currently available, the Agency is requiring the registrant to submit oncogenicity studies in the rat and the mouse for both daminozide and UDMH, a full complement of mutagenicity studies on UDMH, a study in miniature pigs to determine conversion of daminozide to UDMH in mammalian species, a market basket survey, metabolism studies, livestock feeding studies, and residue field trials.

Until these studies are received, the Agency cannot reach any definitive conclusions about the long-term risks posed by the use of daminozide. Based on available data, however, the Agency has concluded that any risk posed to consumers during the time period required for data generation is small, while the benefits are high for the production of an adequate, wholesome, and economical food supply. Accordingly, the Agency believes that it has acted properly to protect the public health. The Agency will, of course, take prompt appropriate regulatory action to amend or revoke the remaining tolerances if the new data indicate that daminozide poses a long-term health hazard to the consumer.

Sincerely yours,

/s/

John A. Moore
Assistant Administrator for
Pesticides and Toxic Substances

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PUBLIC CITIZEN, *et al.*, Plaintiffs, OTIS R. BOWEN, et al., Defendants	v.	Civil Action No. 86-1540 (Judge Harris)

MEMORANDUM IN SUPPORT OF
MOTION TO DISMISS OR TRANSFER

In this case plaintiffs ask this Court: to declare that the defendants have no authority under 21 U.S.C. § 348 to allow the continued use of methylene chloride as a food additive, even if they find that the risk to humans is *de minimis*; to direct the defendants to commence rulemaking proceedings to prohibit the use of methylene chloride to decaffeinate coffee; and, further, to direct defendants to ban the use of methylene chloride in the decaffeination of coffee if, at the conclusion of rulemaking, it is determined that methylene chloride causes cancer in animals. Pursuant to Rule 12(b)(1), Fed. R. Civ. P., the government now moves to dismiss or, in the alternative, pursuant to 28 U.S.C. § 1631, transfer to the court of appeals because plaintiffs here seek relief that might affect the court of appeals' future exercise of its statutory power of review.

INTRODUCTION

In December, 1985 the Food and Drug Administration (FDA) published a proposed rule banning the of methylene chloride as an ingredient in aerosol cosmetic products because

recent studies had shown that the inhalation of methylene chloride causes cancer in laboratory animals. 50 Fed. Reg. 51551 (December 18, 1985) (attached as Exhibit A). On the basis of those studies, FDA concluded that the continued use of methylene chloride in cosmetic products may pose a significant risk to the public health, especially to specific segments of the population that are continually exposed to cosmetics (primarily hairsprays) containing methylene chloride. *Id.* In the same document, the agency published its risk estimate for the food additive use of methylene chloride in the decaffeination of coffee.

Methylene chloride for use in the decaffeination of coffee is regulated as a food additive pursuant to 21 C.F.R. § 173.255(c), which regulation limits residual methylene chloride to a level not to exceed 10 parts per million in decaffeinated roasted coffee and in decaffeinated soluble coffee extract (instant coffee). 21 C.F.R. § 173.255(c) was issued on August 31, 1967, (32 Fed. Reg. 12605) in response to a food additive petition and has been in effect since that time.

Extrapolating from the scientific data used to evaluate the aerosol cosmetics uses, FDA also performed a risk evaluation on the continued use of methylene chloride to decaffeinate coffee, concluding that the risk of cancer from the use of methylene chloride in decaffeination was "so low as to be effectively no risk, and that there would be no benefit to the public from prohibiting its use...." 50 Fed. Reg. 51557. The agency concluded that continued use of the substance could be permitted under a "de minimis" interpretation of the so-called Delaney Clause, 21 U.S.C. § 348(c)(3(A). *Id.*

FDA invited comments on the entire proposal, to be submitted by February 18, 1986. Following receipt of two requests for a 45-

day extension of the comment period with respect to the agency's risk assessment of methylene chloride in decaffeination, the agency extended the comment period to April 4, 1986. 51 Fed. Reg. 6494 (February 24, 1986) (attached as Exhibit B). During the entire comment period, more than 50 comments on the decaffeination issue, consisting of approximately 1000 pages, were submitted.

On April 3, 1986, Public Citizen, one of the plaintiffs in this case, wrote to the Commissioner of Food and Drugs (attached as Exhibit C), arguing that FDA must prohibit the use of methylene chloride as a food additive under the Delaney Clause. On April 29, 1986, the Commissioner of Food and Drugs (Commissioner) replied, stating that a realistic time to evaluate the comments received on the methylene chloride proposal was needed by the agency and that the agency was not in a position to make a final determination regarding the use of methylene chloride to decaffeinate coffee until the comments had been thoroughly evaluated. (attached as Exhibit D). On June 4, 1986, plaintiffs filed this suit.

BACKGROUND

Although it occurs in decaffeinated coffee only as a result of its use as a solvent in the manufacturing process, methylene chloride is a "food additive" under the Act.[1] Under 21 U.S.C. § 348(b), a food additive may not be used until it has been approved by the agency for safety.[2] Thus, manufacturers wishing

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[1]Additives such as solvents are termed "secondary direct food additives." 21 C.F.R. Part 173.

[2]Although the Act vests authority in the Secretary of the Department of Health and Human Services, the authority to make determinations concerning the safety of food additives has been delegated to the Commissioner of Food and Drugs. 21 C.F.R. § 5.10.

to market a food additive must file a petition with the FDA proposing issuance of a regulation prescribing the conditions under which the additive may be safely used. The petitioner must submit data adequate to demonstrate the safety of the additive. If adequate safety data are provided, the Commissioner issues a final regulation approving the additive. 21 U.S.C. § 348 (c) (1) (A). If inadequate data are provided, the Commissioner must deny the petition. 21 U.S.C. § 348(c)(1)(B). In either case, any person who is adversely affected by the agency's decision may file objections with the agency and request a formal evidentiary hearing. 21 U.S.C. § 348(f); 21 C.F.R. § 171.110. After a final agency decision, parties whose interests are adverse to that decision may seek review of the agency's action in the court of appeals pursuant to 21 U.S.C. § 348(g). Procedures for amendment and/or revocation of a food additive are the same as for adoption, 21 U.S.C. § 348(h), and appeal of the Commissioner's ultimate decision to amend or revoke also lies in the court of appeals. 21 U.S.C. § 348(g)(1).

ARGUMENT

Jurisdiction in this Case Lies Exclusively in the Court of Appeals

The plaintiffs here ask this Court to require FDA to commence a proceeding[3] to revoke the food additive governing the use of methylene chloride in decaffeination. Thus, plaintiffs seek to have this Court compel agency action which under 21 U.S.C. § 348 is subject to review in the court of appeals.[4] Where a statute

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[3]As the Commissioner points out in his letter to plaintiffs, Exhibit D, FDA is engaged in ongoing rulemaking on this matter.

[4]21 U.S.C. § 348(g)(1) provides that:

> In a case of actual controversy as to the validity of any order issued under subsection (f) of this section [which involves orders approving, disapproving, amending, or revoking food additive petitions] ... any person who will be adversely affected by such order may obtain judicial review by filing in the United States Court of Appeals ....

commits final agency action to review by the court of appeals, the appellate court has exclusive jurisdiction to hear suits seeking relief that might affect its future statutory power of review. *See Florida Power & Light Co. v. Lorion*, ___ U.S. ___, 105 S.Ct. 1598, 1606 (1985); *Community Nutrition Institute v. Young*, 773 F.2d 1356, 1361 (D.C. Cir. 1985), *cert. denied*, ___ U.S. ____, 106 S.Ct. 1642 (1986); *Telecommunications Research & Action Center v. F.C.C.*, 750 F.2d 70, 72 (D.C. Cir. 1984) (hereinafter cited as *TRAC*).

In *Florida Power*, plaintiffs had appealed to the court of appeals a Nuclear Regulatory Commission (NRC) denial of their request that the NRC institute a proceeding to modify, suspend, or revoke the license of a nuclear reactor. The court of appeals dismissed for lack of subject matter jurisdiction, and the plaintiffs appealed. Reversing the court of appeals, the Supreme Court stated that, absent specific evidence of contrary congressional intent, review of orders resolving issues preliminary or ancillary to the core issue in a proceeding should be reviewed in the same forum as the final order involving the core issue. 105 S.Ct. at 1606. Because the "core issue" in *Florida Power* was a licensing proceeding for which Congress intended initial court of appeals review, review in that forum was appropriate. Allowing initial review of agency matters in the district court would only result in a "duplication of judicial review" by the district court since the factfinding capacity of the district court is "typically unnecessary to judicial review of agency decisionmaking." *Id.* at 1606-1607; *see also Harrison v. PPG Industries, Inc.*, 446 U.S. 578, 593 (1980).

As in *Florida Power*, plaintiffs in the *TRAC* case sought initial review in the court of appeals, seeking to have that court order the Federal Communications Commission to decide certain pending unresolved matters. The plaintiffs alleged that the FCC was

unreasonably delaying a decision on issues in which final agency action on the merits would have been reviewable, by statutory provision in the court of appeals. Reviewing the jurisdictional question, the court of appeals held that where a statute commits review of final agency action to the court of appeals, *any* suit seeking relief which might affect the court's future jurisdiction is subject to its exclusive review. *Id.* at 75.[5]

The court of appeals for this circuit has applied the principles set out in *TRAC* to a case which, as here, involved the food additive provisions of the Act. *Community Nutrition*, 773 F.2d at 1356. In the *Community Nutrition* case, plaintiffs filed suit in the district court seeking various types of interim relief with respect to certain uses of the artificial sweetener aspartame (NutraSweet) after the agency, by regulation, had amended the food additive regulation governing aspartame to include new uses. The district court denied the various motions filed by plaintiffs, and ultimately granted a motion to dismiss filed by the government finding that, since the FDA had entered a final ruling denying plaintiff's request for a hearing, "only the Court of Appeals had jurisdiction." *Id.* at 1360. The court of appeals, however, found that the district court had erred in asserting jurisdiction over the case even before the FDA issued a final order denying a public hearing because jurisdiction over all food additive matters lay exclusively in the court of appeals. *Id* at 1362.[6]

Here, plaintiffs ask not only that the Court order the agency to act on a matter subject to review only in the court of appeals, they also ask that the Court direct the outcome (revocation of the

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[5]The court's holding concerning the court of appeals' jurisdiction was considered separately and approved by the whole court. *TRAC*, 750 F.2d at 75, n.24.

[6]Thus, the breadth of review in the court of appeals over food additive matters is not limited, as 28 U.S.C. §§ 348(f) and (g) might suggest, to final orders issued after a public hearing.

regulation) if the agency finds that methylene chloride causes cancer. The rule in this circuit prohibits this Court from doing either. *TRAC*, 750 F.2d 75, n.24.[7]

CONCLUSION

Because exclusive jurisdiction to review matters involving food additive petitions lies in the court of appeals, this Court should dismiss this action or transfer it to the court of appeals pursuant to 28 U.S.C. § 1631.

Respectfully submitted this 4th day of August, 1986.

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[7]Although the government also believes that this case should be dismissed because the issues presented are not ripe for review and plaintiffs have failed to exhaust their administrative remedies, those issues are not briefed here because we believe that, though this case should be dismissed on ripeness and exhaustion grounds, it is the court of appeals that has the exclusive jurisdiction to rule on those issues and to dismiss this case on those grounds.

FEDERAL FOOD, DRUG AND COSMETIC ACT

SECTION 408 [21 U.S.C. § 346a].

TOLERANCES FOR PESTICIDE CHEMICALS IN OR ON RAW AGRICULTURAL COMMODITIES

* * *

(d)(1) Any person who has registered, or who has submitted an application for the registration of, an economic poison under the Federal Insecticide, Fungicide, and Rodenticide Act may file with the Administrator a petition proposing the issuance of a regulation establishing a tolerance for a pesticide chemical which constitutes, or is an ingredient of such economic poison, or exempting the pesticide chemical from the requirement of a tolerance. The petition shall contain data showing —

(A) the name, chemical, identity, and composition of the pesticide chemical;

(B) the amount, frequency, and time of application of the pesticide chemical;

(C) full reports of investigations made with respect to the safety of the pesticide chemical;

(D) the results of the tests on the amount of residue remaining, including a description of the analytical methods used;

(E) practicable methods for removing residue which exceeds any proposed tolerance;

(F) proposed tolerances for the pesticide chemical if tolerances are proposed; and

(G) reasonable grounds in support of the petition.

Samples of the pesticide chemical shall be furnished to the Administrator upon request. Notice of the filing of such petition shall be published in general terms by the Administrator within

thirty days after filing. Such notice shall include the analytical methods available for the determination of the residue of the pesticide chemical for which tolerance or exemption is proposed.

(2) Within ninety days after a certification of usefulness by the Administrator under subsection (1) with respect to the pesticide chemical named in the petition, the Administrator shall, after giving due consideration to the data submitted in the petition or otherwise before him, by order make public a regulation —

(A) establishing a tolerance for the pesticide chemical named in the petition for the purposes for which it is so certified as useful, or

(B) exempting the pesticide chemical from the necessity of a tolerance for such purposes, unless within such ninety-day period the person filing the petition requests that the petition be referred to an advisory committee or the Administrator within such period otherwise deems such referral necessary, in either of which events the provisions of paragraph (3) of this subsection shall apply in lieu hereof.

(3) In the event that the person filing the petition requests, within ninety days after a certification of usefulness by the Administrator under subsection (1), with respect to the pesticide chemical named in the petition, that the petition be referred to an advisory committee, or in the event the administrator within such period otherwise deems such referral necessary, the Administrator shall forthwith submit the petition and other data before him to an advisory committee to be appointed in accordance with subsection (g) of this section. As soon as practicable after such referral, but not later than sixty days thereafter, unless extended as hereinafter provided, the committee shall, after independent study of the data submitted to it by the Administrator and other data before it, certify to the Administrator a report and recommendations on the proposal in the petition to the Administrator,

together with all underlying data and a statement of the reasons or basis for the recommendations. This sixty-day period provided for herein may be extended by the advisory committee for an additional thirty days if the advisory committee deems this necessary. Within thirty days after such certification, the Administrator shall, after giving due consideration to all data then before him, including such report, recommendations, underlying data, and statement, by order make public a regulation —

(A) establishing a tolerance for the pesticide chemical named in the petition for the purposes for which it is so certified as useful; or

(B) exempting the pesticide chemical from the necessity of a tolerance for such purposes.

(4) The regulations published under paragraph (2) or (3) of this subsection will be effective upon publication.

(5) Within thirty days after publication, any person adversely affected by a regulation published pursuant to paragraph (2) or (3) of this subsection, or pursuant to subsection (e), may file objections thereto with the Administrator, specifying with particularity the provisions of the regulation deemed objectionable, stating reasonable grounds therefor, and requesting a public hearing upon such objections. A copy of the objections filed by a person other than the petitioner shall be served on the petitioner, if the regulation was issued pursuant to a petition. The petitioner shall have two weeks to make a written reply to the objections. The Administrator shall thereupon after due notice, hold such public hearing for the purpose if receiving evidence relevant and material to the issues raised by objections. Any report, recommendations, underlying data, and reasons certified to the Administrator by an advisory committee shall be made a part of the record of the hearing, if relevant and material, subject to the provisions of section 7(c) of the Administrative Procedure Act (5 U.S.C. sec. 1006(c)). The National Academy of Sciences shall designate a member of the advisory committee to appear

and testify at any such hearing with respect to the report and recommendations of such committee upon request of the Administrator, the petitioner, or the officer conducting the hearing: *Provided*, That this shall not preclude any other member of the advisory committee from appearing and testifying at such hearing. As soon as practicable after completion of the hearing, the Administrator shall act upon such objections and by order make public a regulation. Such regulation shall be based only on substantial evidence of record at such hearing, including any report, recommendations, underlying data, and reasons certified to the Administrator by an advisory committee, and shall set forth detailed findings of fact upon which the regulation is based. No such order shall take effect prior to the ninetieth day after its publication, unless the Administrator finds that emergency conditions exist necessitating an earlier effective date, in which event the Administrator shall specify in the order of his findings as to such conditions.

(e) The Administrator may at any time, upon his own initiative or upon the request of any interested person, propose the issuance of a regulation establishing a tolerance for a pesticide chemical or exempting it from the necessity of a tolerance. Thirty days after publication of such a proposal, the Administrator may by order publish a regulation based upon the proposal which shall become effective upon publication unless within such thirty-day period a person who has registered, or who has submitted an application for the registration of, an economic poison under the Federal Insecticide, Fungicide, and Rodenticide Act containing the pesticide chemical named in the proposal, requests that the proposal be referred to an advisory committee. In the event of such a request, the Administrator shall forthwith submit the proposal and other relevant data before him to an advisory committee to be appointed in accordance with subsection (g) of this section. As soon as practicable after such referral, but not later than sixty days thereafter, unless extended

as hereinafter provided, the committee shall, after independent study of the data submitted to it by the Administrator and other data before it, certify to the Administrator a report and recommendations on the proposal together with all underlying data and a statement of the reasons or basis for the recommendations. The sixty-day period provided for herein may be extended by the advisory committee for an additional thirty days if the advisory committee deems this necessary. Within thirty days after such certification the Administrator may, after giving due consideration to all data before him, including such report, recommendations, underlying data and statement, by order publish a regulation establishing a tolerance for the pesticide chemical named in the proposal or exempting it from the necessity of a tolerance which shall become effective upon publication. Regulations issued under this subsection shall upon publication be subject to paragraph (5) of subsection (d).

* * *

(i)(l) In a case of actual controversy as to the validity of any order under subsection (d)(5), (e) or (1) any person who will be adversely affected by such order may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein such person resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after entry of such order, a petition praying that the order be set aside in whole or in part.

(2) In the case of a petition with respect to an order under subsection (d)(5) or (e), a copy of the petition shall be forthwith transmitted by the clerk of the court to the Administrator, or any officer designated by him for that purpose, and thereupon the Administrator shall file in the court the record of the proceedings on which he based his order, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition, the court

shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. The findings of the Administrator with respect to questions of fact shall be sustained if supported by substantial evidence when considered on the record as a whole, including any report and recommendation of an advisory committee.

(3) In the case of a petition with respect to an order under subsection (1), a copy of the petition shall be forthwith transmitted by the clerk of the court to the Administrator or any officer designated by him for that purpose, and thereupon the Administrator shall file in the court the record of the proceedings on which he based his order, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition, the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. The findings of the Administrator with respect to questions of fact shall be sustained if supported by substantial evidence when considered on the record as a whole.

(4) If application is made to the court for leave to adduce additional evidence, the court may order such additional evidence to be taken before the Administrator, and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper, if such evidence is material and there were reasonable grounds for failure to adduce such evidence in the proceedings below. The Administrator may modify his findings as to the facts and order by reason of the additional evidence so taken, and shall file with the court such modified findings and order.

(5) The judgment of the court affirming or setting aside, in whole or in part, any order under this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this section shall not, unless specifically ordered by the

court to the contrary, operate as a stay of an order. The court shall advance on the docket and expedite the disposition of all causes filed therein pursuant to this section.

* * *

(l) The Administrator, upon request of any person who has registered, or who has submitted an application for the registration of, an economic poison under the Federal Insecticide, Fungicide, and Rodenticide Act, and whose request is accompanied by a copy of a petition filed by such person under subsection (d)(1) with respect to a pesticide chemical which constitutes, or is an ingredient of, such economic poison shall, within thirty days or within sixty days if upon notice prior to the termination of such thirty days the Administrator deems it necessary to postpone action for such period, on the basis of data before him either—

> (1) certify that such pesticide chemical is useful for the purpose for which a tolerance or exemption is sought; or
>
> (2) notify the person requesting the certification of his proposal to certify that the pesticide chemical does not appear to be useful for the purpose for which a tolerance or exemption is sought, or appears to be useful for only some of the purposes for which a tolerance or exemption is sought.

In the event that the Administrator takes the action described in clause (2) of the preceding sentence, the person requesting the certification, within one week after receiving the proposed certification, may either (A) request the Administrator to certify on the basis of the proposed certification; (B) request a hearing on the proposed certification or the parts thereof objected to; or (C) request both such certification and such hearing. If no such action is taken, the Administrator may by order make the

certification as proposed. In the event that the action described in clause (A) or (C) is taken, the Administrator shall by order make the certification as proposed with respect to such parts thereof as are requested. In the event a hearing is requested, the Administrator shall provide opportunity for a prompt hearing. The certification of the Administrator as the result of such hearing shall be made by order and shall be based only on substantial evidence of record at the hearing and shall set forth detailed findings of fact. In no event shall the time elapsing between the making of a request for a certification under this subsection and final certification by the Administrator exceed one hundred and sixty days. The Administrator shall submit with any certification of usefulness under this subsection an opinion, based on the data before him whether the tolerance or exemption proposed by the petitioner reasonably reflects the amount of residue likely to result when the pesticide chemical is used in the manner proposed for the purpose for which the certification is made. The Administrator, after due notice and opportunity for public hearing, is authorized to promulgate rules and regulations for carrying out the provisions of this subsection.

* * *

SECTION 409 [21 U.S.C. § 348].

FOOD ADDITIVES

* * *

Action on Petition

(c)(1) the Secretary shall —

(A) by order establish a regulation (whether or not in accord with that proposed by the petitioner) prescribing, with respect to one or more proposed uses of the food additive involved, the conditions under which such additive may be safely used (including, but not limited to, specifications as to the particular food or classes of food in or on which such additive may be used, the maximum quantity which may be used or permitted to remain in or on such food, the manner in which such additive may be added to or used in or on such food, and any directions or other labeling or packaging requirements for such additive deemed necessary by him to assure the safety of such use), and shall notify the petitioner of such order and the reasons for such action; or

(B) by order deny the petition, and shall notify the petitioner of such order and of the reasons for such action.

(2) The order required by paragraph (1)(A) or (B) of this subsection shall be issued within ninety days after the date of filing of the petition, except that the Secretary may (prior to such ninetieth day), by written notice to the petitioner, extend such ninety-day period to such time (not more than one hundred and eighty days after the date of filing of the petition) as the Secretary deems necessary to enable him to study and investigate the petition.

(3) No such regulation shall issue if a fair evaluation of the data before the Secretary —

(A) fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe: *Provided*, That no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal, except that this proviso shall not apply with respect to the use of a substance as an ingredient of feed for animals which are raised for food production, if the Secretary finds (i) that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and (ii) that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsections (f) and (g)) in any edible portion of such animal after slaughter or in any food yielded by or derived from the living animal; or

(B) shows that the proposed use of the additive would promote deception of the consumer in violation of this Act or would otherwise result in adulteration or in misbranding of food within the meaning of this Act.

(4) If, in the judgment of the Secretary, based upon a fair evaluation of the data before him, a tolerance limitation is required in order to assure that the proposed use of an additive will be safe, the Secretary—

(A) shall not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the physical or other technical effect for

which such additive is intended; and

(B) shall not establish a regulation for such proposed use if he finds upon a fair evaluation of the data before him that such data do not establish that such use would accomplish the intended physical or other technical effect.

(5) In determining, for the purposes of this section, whether a proposed use of a food additive is safe, the Secretary shall consider among other relevant factors —

(A) the probable consumption of the additive and of any substance formed in or on food because of the use of the additive;

(B) the cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substance or substances in such diet; and

(C) safety factors when in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives are generally recognized as appropriate for the use of animal experimentation data.

Regulation Issued on Sectretary's Initiative

(d) The Secretary may at any time, upon his own initiative, propose the issuance of a regulation, prescribing, with respect to any particular use of a food additive, the conditions under which such additive may be safely used, and the reasons therefor. After the thirtieth day following publication of such a proposal, the Secretary may by order establish a regulation based upon the proposal.

Publication and Effective Date of Orders

(e) Any order, including any regulation established by such order, issued under subsection (c) or (d) of this section, shall be published and shall be effective upon publication, but the Secretary may stay such effectiveness if, after issuance of such order, a hearing is sought with respect to such order pursuant to subsection (f).

(f)(1) Within thirty days after publication of an order made pursuant to subsection (c) or (d) of this section, any person adversely affected by such an order may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating reasonable grounds therefor, and requesting a public hearing upon such objections. The Secretary shall, after due notice, as promptly as possible hold such public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public.

(2) Such order shall be based upon a fair evaluation of the entire record at such hearing, and shall include a statement setting forth in detail the findings and conclusions upon which the order is based.

(3) The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication, unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

Judicial Review

(g)(1) In a case of actual controversy as to the validity of any order issued under subsection (f), including any order thereunder with respect to amendment or repeal of a regulation issued under this section, any person who will be adversely affected by such order may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein such person resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a petition praying that the order be set aside in whole or in part.

(2) A copy of such petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated by him for that purpose, and thereupon the Secretary shall file in the court the record of the proceedings on which he based his order, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition the court shall have jurisdiction, which upon the filing of the record with it shall be exclusive, to affirm or set aside the order complained of in whole or in part. Until the filing of the record the Secretary may modify or set aside his order. The findings of the Secretary with request to questions of fact shall be sustained of based upon a fair evaluation of the entire record at such hearing. The court shall advance on the docket and expedite the disposition of all causes filed therein pursuant to this section.

(3) The court, on such judicial review, shall not sustain the order of the Secretary if he failed to comply with any requirement imposed on him by subsection (f)(2) of this section.

(4) If application is made to the court for leave to adduce additional evidence, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper, if such evidence is material and

there were reasonable grounds for failure to adduce such evidence in the proceedings below. The Secretary may modify his findings as to the facts and order by reason of the additional evidence so taken, and shall file with the court such modified findings and order.

(5) The judgment of the court affirming or setting aside, in whole or in part, any order under this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this section shall not, unless specifically ordered by the court to the contrary, operate as a stay of an order.

Amendment or Repeal of Regulations

(h) The Secretary shall by regulation prescribe the procedure by which regulations under the foregoing provisions of this section may be amended or repealed, and such procedure shall conform to the procedure provided in this section for the promulgation of such regulations.

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